



NORTH CAROLINA
Environmental Quality

North Carolina Department of Environmental Quality
Division of Water Resources – Water Sciences Section
Wastewater/Groundwater Laboratory Certification Branch

Proficiency Testing Requirements
Revision 5

2/19/2020



Table of Contents

Section	Content	Page Number
1.0	Introduction	4
2.0	Definitions	4
3.0	Proficiency Testing (PT) Requirements	9
3.1	Initial Certification	11
3.2	Certification Maintenance/Renewal	11
3.3	Decertification	13
3.4	Recertification	15
3.5	EPA Lab Code	15
3.6	General PT Analysis and Reporting Requirements	16
3.7	Parameter-Specific PT Requirements	19
3.7.1	Total Residual Chlorine (low-level)	19
3.7.2	Microbiological Samples	20
3.7.3	Biochemical Oxygen Demand (BOD)	20
3.7.4	Chlorophyll a	20
3.8	Matrix-Specific PT Requirements	21
3.9	DMR-QA PT Study Exemption for NC Permittees	21
4.0	PT Sample Record Retention	22
5.0	Evaluating and Grading PT Sample Results	22
5.1	Selective Ion Mode (SIM) Analysis	23
5.2	Single-Analyte PT Samples	23
5.3	Multi-Analyte Group PT Samples	23
5.3.1	80% Rule	23
5.3.2	Individual Analyte Corrective Actions and Provisional Certification	26
5.4	Multiple Concentration Levels	26
5.5	Parameter-Specific PT Evaluations	27
5.6	Matrix-Specific PT Evaluations	28
5.7	Multiple Studies Analyzed at the Same Time	28
6.0	Complaint Resolution	28
7.0	Auditor Oversight and Tracking	28
8.0	References	30
9.0	Revision History	30
Attachments		
1	Notice of Missed Proficiency Testing Deadline Letter	44
2	Notice of Intent to Decertify Inorganic Method Letter	45
3	Notice of Intent to Decertify Organic Method Letter	46
4	Decertification Effective Date Letter	47
5	Decertified Laboratory Report (For Commercial Laboratories)	49
6	Decertified Laboratory Report (For Municipal, Industrial and Other Laboratories)	50
7	Decertified Laboratory Report (For Field Laboratories)	51
8	Notice of Decertification for Failure to Submit Information by the Due Date	52
9	Parameter Method Recertification Letter	53
10	EPA DMR-QA PT Study Exemption Letter	54
11	PT Evaluation Letter – Unacceptable Results	56
12	PT Evaluation Letter – Acceptable Results Complete	58
13	PT Evaluation Letter – Acceptable Results Incomplete	59

14	Provisional Certification Notification Letter	60
15	Provisional Certification Form - Commercial	61
16	Provisional Certification Form – Municipal/Industrial/Other	62
17	Provisional Certification Rescission Letter	63
18	Example Root Cause Analysis and CAR Form	64
19	PT Checklist for Non-Field Laboratories	66
20	PT Checklist for Field Laboratories	67

1.0 Introduction

This document is a guide to the Proficiency Testing (PT) requirements of the North Carolina Wastewater/Groundwater Laboratory Certification (NC WW/GW LC) Program, administered by the NC Department of Environmental Quality (DEQ), Division of Water Resources, Water Sciences Section, Laboratory Certification Branch. In addition to clarifying the regulatory requirements for Proficiency Testing, this document answers many common questions concerning evaluation of PT Sample results. Also included are important deadlines, penalties and corrective actions for PT failures, and links to the current list of all Accredited PT Sample Providers.

PT Samples are standards whose true value concentrations are unknown to the laboratory and are supplied by an Accredited PT Sample Provider. PT Samples are analyzed by a laboratory to evaluate its ability to accurately perform analyses for specified analytes by a particular parameter method. They are an integral part of a laboratory's quality management system and the laboratory Certification process. The NC WW/GW LC Program uses the results of these samples to assess a laboratory's analytical performance between on-site evaluations. All laboratories must submit acceptable PT Sample results annually to maintain their Certifications. The laboratory must obtain PT Samples from an Accredited PT Sample Provider recognized by The National Environmental Laboratory Accreditation Congress Institute (TNI) and approved by the NC WW/GW LC Program. These PT Samples may be part of an official study, a supplemental study or Quick Response PT Samples. PT Samples from providers not accredited by a Proficiency Testing Provider Accreditor (PTPA) cannot be accepted. A list of Accredited PT Sample Providers may be found on the TNI website at <http://nelac-institute.org/content/NEPTP/ptproviders.php>. A list of required PT Samples per parameter method is updated annually and can be found on the following Laboratory Certification Proficiency Testing Requirements web pages:

Field Laboratory PT Requirements: <http://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/pt-requirements>

Non-Field Laboratory PT Requirements: <http://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/pt-requirements-0>

The NC WW/GW LC Program reserves the right to determine acceptable performance of a laboratory on any PT or Split Sample which includes, but is not limited to, the elements contained in this policy. A laboratory's Certification status is determined not only by its performance in acceptable proficiency tests but by a combination of criteria including qualifications of personnel, its performance in on-site inspections, and, in the case of laboratories located outside of North Carolina seeking initial Certification by reciprocity, the status of its certification from its resident state. For more information about the NC WW/GW LC Program's processes and requirements, visit <http://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch>.

2.0 Definitions

- 2.1 Acceptable Results:** Proficiency Testing (PT) Sample results that are within the Vendor-specified acceptable range as indicated by a Vendor, or Split Samples that are within the specified acceptance range as provided by the State Laboratory.
- 2.2 Acceptance Limits:** Limits established by an Accredited Proficiency Testing (PT) Provider, based upon the US EPA National Standards for Water Proficiency Testing Program Criteria Document (NERL-Ci-0045), which are used to determine if a laboratory has analyzed a PT Sample successfully. For the Water Pollution Program (WP), EPA Acceptance Limits are defined as \pm three EPA Standard Deviations from the EPA Mean.
- 2.3 Accredited Proficiency Testing (PT) Sample Provider:** Where the North Carolina Administrative Code requires use of an Accredited PT Sample Provider, this shall mean a proficiency testing program accredited by a Proficiency Testing Provider Accreditor (PTPA) that meets the TNI requirements for the design, preparation, and operation of PT schemes. A list of Accredited PT Providers can be found here:
<http://www.nelac-institute.org/content/NEPTP/ptproviders.php>
- 2.4 Analysis Date:** The calendar date of analysis associated with the analytical result reported for Certification requirements.
- 2.5 Analyte:** The chemical substance, physical property or organism being analyzed in a reference sample.
- 2.6 Analyte Group:** A set of chemical substances possessing structural and reactive similarities that are analyzed as a group using the same method of analysis or technology (e.g., VOCs, PCBs, etc.).
- 2.7 Certification:** A declaration by the State Laboratory that the personnel, equipment, records, quality control procedures, and methodology cited by the applicant are accurate and that the applicant's proficiency has been considered and found to be acceptable pursuant to NC Administrative Code 15 NCAC 2H .0800.
- 2.8 Certified Data:** Any analytical result, including the Supporting Records, obtained using a method or procedure pursuant to NC Administrative Code 15 NCAC 2H .0800.
- 2.9 Certified Parameters Listing (CPL):** A list of all the analytical methods that a laboratory is Certified to perform and report to clients or the State of North Carolina as Certified Data.
- 2.10 Commercial Laboratory:** Any laboratory, including its agents or employees, which is seeking to analyze or is analyzing samples in a chemistry laboratory or in a field setting, including Field Parameters, for others for a fee.
- 2.11 Compliance Sample:** For the purposes of this document, Compliance Samples are defined as environmental samples that are analyzed for the purpose of reporting to the State pursuant to 15A NCAC 02H .0800.
- 2.12 Corrective Action Report (CAR):** A report detailing the measures taken to eliminate or prevent the recurrence of the causes of an existing out-of-control event, nonconformity or

undesirable condition. It is a retrievable documentation of those actions and follow-up monitoring to ensure resolution. A good corrective action report addresses and documents the following: the existing problem, the root cause of the problem, corrective actions taken to correct the problem, actions taken to prevent recurrence, future monitoring to check resolution and data that required qualification or rejection as a result of this problem. References to CARs in this document relate to Proficiency Testing evaluations.

- 2.13 Decertification:** Loss of Certification.
- 2.14 Discharge Monitoring Report–Quality Assurance (DMR-QA) Proficiency Testing (PT) Study Program:** The DMR-QA PT Study Program evaluates the analytical and reporting ability of the laboratories that routinely perform inorganic chemistry and whole effluent toxicity self-monitoring analyses required by their National Pollutant Discharge Elimination System (NPDES) permit. North Carolina permittees are exempt from the DMR-QA PT Study Program but must meet all other requirements of this document.
- 2.15 EPA:** Acronym for the United States Environmental Protection Agency.
- 2.16 EPA Lab Code:** A laboratory identification system used to identify participant laboratories in Proficiency Testing Studies when grading and reporting results. EPA Lab Codes are assigned by the EPA.
- 2.17 Field Laboratory:** A laboratory, including its agents or employees, which is seeking Certification to analyze or is analyzing samples in a chemistry laboratory or a field setting for Field Parameters only.
- 2.18 Field Parameters:** For the purpose of the North Carolina Wastewater/Groundwater Laboratory Certification Rules (15 NCAC 2H .0800), Field Parameters shall include Total Residual Chlorine, Free Available Chlorine, Conductivity, Dissolved Oxygen, pH, Settleable Residue, Salinity, Sulfite, Turbidity, Temperature, Vector Attraction Reduction Option 5, Vector Attraction Reduction Option 6, and Vector Attraction Reduction Option 12.
- 2.19 Industrial Laboratory:** A laboratory, including its agents or employees, operated by an industry to analyze samples in a chemistry laboratory or in a field setting, including Field Parameters, from its wastewater or wastewater from its water treatment plant(s) pursuant to NC Administrative Code 15 NCAC 2H .0800.
- 2.20 Multi-analyte Group Proficiency Testing (PT) Sample:** A PT Sample containing more than one analyte of interest where Certification is granted for the analytes as a group based on acceptable results for all of the existing analytes (e.g., PCBs).
- 2.21 Multi-analyte Proficiency Testing (PT) Sample:** A PT Sample containing more than one analyte of interest where Certification is granted for an analyte based on methodology (e.g., Organochlorine Pesticides).
- 2.22 Municipal Laboratory:** A laboratory, including its agents or employees, operated by a municipality or other local government to analyze samples in a chemistry laboratory or in

a field setting, including Field Parameters, from its wastewater or wastewater from its water treatment plant(s) pursuant to NC Administrative Code 15 NCAC 2H .0800.

- 2.23 NC WW/GW Laboratory Certification Number:** A unique identifying number assigned to each laboratory Certified by the NC WW/GW LC Program.
- 2.24 Non-Field Laboratory:** A laboratory, including its agents or employees, that analyzes samples for any parameters including and/or beyond those defined as Field Parameters.
- 2.25 Not Acceptable:** Those results on Proficiency Testing (PT) Samples that exceed the specified acceptable range as indicated by an Accredited PT Sample Provider, as well as, any false negative or false positive results.
- 2.26 Other Laboratory:** A facility that is not required to obtain State Laboratory Certification as part of its routine operation and does not analyze samples in a chemistry laboratory or in a field setting for a fee or is doing business as a non-profit facility.
- 2.27 Parameter:** Analyte, element, compound, or property being measured.
- 2.28 Parameter Method:** A type of analytical technique, including materials and tools, used to measure a parameter.
- 2.29 Practical Quantitation Limit:** The Practical Quantitation Limit (PQL) is defined and proposed as "the lowest level achievable among laboratories within specified limits during routine laboratory operation". The PQL is about three to five times the calculated Method Detection Limit (MDL) and represents a practical and routinely achievable detection limit with a relatively good certainty that any reported value is reliable". For methods requiring a calibration curve, a calibration standard must be analyzed at the PQL concentration.
- 2.30 Primary Analyte List:** The list of analytes in the scope of a published method.
- 2.31 Proficiency Testing (PT) Calendar Year:** For the purposes of performance evaluation, the calendar year is defined as January 1 to September 30.
- 2.32 Proficiency Testing Provider Accreditor (PTPA):** The detailed requirements for The NELAC Institute's (TNI's) designated Proficiency Testing Provider Accreditors (PTPA) in the TNI Proficiency Testing (PT) Program are in Volume 4 of TNI's Environmental Sector Standards and in Module 2 of the Stationary Source Audit Sample Standards. The designated PTPA is expected to ensure that its accredited PT Providers that provide PT Samples under the TNI PT Program meet the requirements in Volume 3 of TNI's Environmental Sector Standards and its accredited SSAS providers that provide audit samples under the TNI program meet the requirements in Module 3 of the SSAS Standards. The process by which TNI evaluates an organization to become a TNI-recognized PTPA is found in TNI SOP 4-104, Evaluating Proficiency Testing Provider Accreditors. The TNI Standards and TNI SOP 4-104 are available at The NELAC Institute's internet site (www.nelac-institute.org).

- 2.33 Proficiency Testing (PT) Samples:** A performance evaluation sample whose true value is unknown to the laboratory and provided by a State Laboratory-approved Vendor to test whether the laboratory can produce analytical results within the specified acceptance criteria. PT Sample true value concentrations are not made known until all laboratories analyzing the same PT Samples have submitted their results and the final report is issued. PT Samples are also known as Performance Evaluation (PE) Samples.
- 2.34 Proficiency Testing (PT) Study:** A single complete sequence of circulation of PT Samples to all participants in a PT program.
- 2.35 Proficiency Testing (PT) Study Closing Date:** The calendar date on or by which analytical results for a PT Sample shall be received by the Accredited PT Sample Provider from the laboratory.
- 2.36 Provisional Certification:** A temporary conditional status of Certification which requires a laboratory to qualify specified individual analyte results as “estimated” until acceptable performance is demonstrated or until method Certification is dropped or revoked. This Provisional status is initiated when two consecutive unacceptable results are obtained for one or more individual analytes, in a multi-analyte Proficiency Testing Sample, when the method evaluation is graded acceptable (refer to the 80% Rule in Sections 5.3.1 and 5.3.2).
- 2.37 Quick Response Proficiency Testing (PT) Sample:** A PT Sample that is not part of a scheduled study, but the results are evaluated and reported back to the participant laboratory within a short time after the results are reported. They may also be referred to as Rapid Turnaround Time, Rapid Response or PT Express Samples.
- 2.38 Recertification:** The re-instatement of Certification at the end of the Decertification period imposed by the Division pursuant to 15A NCAC 02H .0807 by showing to the satisfaction of the State Laboratory that the laboratory has corrected the deficiency(ies).
- 2.39 Remedial Proficiency Testing (PT) Sample:** A PT Sample, analyzed as a follow-up to PT Samples for which unacceptable results were obtained, intended to demonstrate correction or improvement of the analysis of the analyte in question using the same specific parameter method. A Remedial PT Sample also applies to a follow-up PT Sample analyzed when the September 30th deadline was exceeded and counted as a first unacceptable result.
- 2.40 Root Cause Analysis (RCA):** A technique used in problem solving to identify the underlying reason why something has gone wrong or why a difficulty has occurred. It is a step-by-step method that leads to the discovery of a fault's first or core cause. In compliance testing, the root cause analysis often takes the investigator back to the laboratory's quality system protocols.
- 2.41 Round Robin Study:** A sample testing study involving multiple independent analysts and/or laboratories performing analytical testing for a given parameter with the use of the same method with different equipment, or a variety of methods and equipment. This type study is used to measure the precision of the measurement of a given target analyte or group of analytes and/or relative performance of the participating entities. The overall

objective is to make test results from different testing laboratories comparable; thereby creating the necessary confidence in the accuracy of test results between the parties involved.

- 2.42 Single Analyte Reference Sample:** A Proficiency Testing Sample containing only one analyte of interest where Certification is granted for an analyte based on methodology.
- 2.43 Split Sample:** A Split Sample is two or more representative portions taken from a sample or subsample and analyzed by two or more laboratories approved by the State Laboratory and are used to measure the precision of the measurement of a given target analyte or group of analytes and/or relative performance of the participating entities.
- 2.44 State:** The North Carolina Department of Environmental Quality, or its successor.
- 2.45 State Laboratory:** The Water Sciences Section, including the Laboratory Certification Branch of the North Carolina Division of Water Resources, or its successor.
- 2.46 Study:** This term applies to a Proficiency Testing Study or Supplemental Proficiency Testing Study.
- 2.47 Supplemental Proficiency Testing (PT) Study:** A PT Sample that may be from a lot previously released by an Accredited PT Sample Provider that meets the requirements for supplemental PT samples, but that does not have a pre-determined opening date and closing date.
- 2.48 Supporting Record:** Any document or other source of information compiled, recorded, or stored in written form, by electronic process, or in any other manner that provides any information necessary to reconstruct or characterize a reported value.
- 2.49 Unacceptable Proficiency Testing (PT) Sample Result:** Those results on Proficiency Testing Samples that do not fall within the Vendor-specified acceptable range as stated by a State Laboratory-approved Vendor, or Split Samples that do not fall within the specified acceptable range as indicated by the State Laboratory, or a failure to meet a reporting deadline imposed by the Vendor or State Laboratory. Results graded as Unacceptable by the PT Vendor for “less than” and “greater than” values may be re-evaluated as Acceptable by the NC WW/GW LC Program (See Section 5.0).
- 2.50 Uncertified Data:** Any analytical result, including the Supporting Records, obtained using a method or procedure, which is not acceptable to the State Laboratory pursuant to NC Administrative Code 15 NCAC 2H .0800.
- 2.51 Vendor:** An accredited Proficiency Testing Sample provider recognized by The NELAC Institute (TNI). See also Section 2.3, Accredited Proficiency Testing (PT) Sample Provider.

3.0 Proficiency Testing (PT) Requirements

All Certified laboratories are required to demonstrate technical competence through PT Sample analyses sufficient to cover the scope of their accreditation. PT Samples are required for initial

Certification, Certification maintenance/renewal and Recertification. At least once in each 9-month PT Calendar Year, and more often if requested by the NC WW/GW LC Program. Each laboratory must have at least one laboratory analyst demonstrate proficiency by successfully analyzing a PT Sample provided by an Accredited PT Sample Provider. Additional PT Sample results submitted voluntarily at any time during the PT Calendar Year (including Water Supply [WS] study samples when the appropriate method is employed during analysis) will be graded similarly.

The NC WW/GW LC Program shall make available a list of Accredited PT Sample Providers and/or provide access to the list on the NC Division of Water Resources Water Sciences Section, Laboratory Certification Branch website for Field Laboratory PT Requirements and Non-Field Laboratory PT Requirements (see URLs below). Accredited PT Providers offer several PT Sample options that will meet NC WW/GW LC Program initial Certification, Certification maintenance/renewal and Recertification requirements. These include the Quick Response PT Samples and WS study samples when the appropriate parameter method is employed during analysis. However, **WS studies will not be accepted for any organic methods except EPA 504.1**. Corrective-action PTs, that are provided with the true values in a sealed envelope, are not considered PT Samples as they are defined in this document and do not meet the PT requirements outlined in 15 NCAC 2H .0800. PT Samples that are not taken through the entire preparation procedure (e.g., 'ready to use' PTs) are also not acceptable. For a detailed list of the PT Samples required for initial Certification, Certification maintenance/renewal, remedial requirements and Recertification, consult the following Laboratory Certification PT Requirements web pages:

Field Laboratory PT Requirements: <http://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/pt-requirements>

Non-Field Laboratory PT Requirements: <http://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/pt-requirements-0>

When such PT Samples are not available or relevant to the scope of accreditation, the NC WW/GW LC Program will rely on the laboratory's quality system checks in accordance with State regulations or the approved methodology for assuring the quality of testing, calibration results and/or Split Samples provided by the Division of Water Resources. Quality control checks include (but are not limited to) the following types of activities: regular use of certified reference materials and/or internal quality control using secondary reference materials; replicate tests or calibrations using the same or different methods; re-testing or re-calibration of retained items; and correlation of results for different characteristics of an item. The results of these quality control checks do not need to be provided to this office but must be retained so that they are readily available for examination during on-site inspection according to NC WW/GW LC Program mandated record retention schedules. Split Sample testing or Round Robin testing may also be required.

Laboratories must have a documented plan [this is usually detailed in the laboratory's Quality Assurance Manual or may be a separate Standard Operating Procedure (SOP)] of how they intend to cover the applicable program requirements for Proficiency Testing per their scope of accreditation. This plan shall cover any commercially available PT Samples and any inter-laboratory organized studies, as applicable. The laboratory must also be able to explain when PT

Sample analysis is not possible for certain methods and provide a description of what the laboratory is doing in lieu of Proficiency Testing. This shall be detailed in the plan. The plan must also address the laboratory's process for submission of PT Sample results and related Corrective Action Reports (CARs).

SOPs must address situations where the instructions from the Accredited PT Provider for the preparation, analysis or result calculations would constitute a deviation from the laboratory's routine procedure. Examples of this may include how low-level PT Samples will be analyzed, including concentration of the sample or adjustment of the normality of a titrant. These instructions shall be followed when the concentration of a PT Sample is below the range of their routine analytical method. Instructions shall also be included in the laboratory's SOP for how high-level PT Samples will be analyzed, including preparation of multiple dilutions of the sample. These instructions will be followed when the concentration of a PT Sample is above the range of their routine analytical method.

3.1 Initial Certification

NC WW/GW LC Program regulations for the Certification and operation of environmental laboratories in the North Carolina Administrative Code, 15 NCAC 2H .0800, state that a laboratory applying for Certification must satisfactorily analyze samples from a NELAC approved Proficiency Testing Provider Accreditor (PTPA) that meets TNI requirements and those of the NC WW/GW LC Program for the parameters, analytes, and methods for which Certification is sought. A specific PT Sample matrix is required in cases where a method is matrix-specific (e.g., SW-846 9071B and SW-846 7471B) and/or when requesting only one matrix when two are available. The exception to this is SW-846 Method 9045D. A PT Sample for that method is not required. The study close dates of all testing results submitted with applications must have occurred within the six months prior to the date of application. When determining whether PT Sample results are sufficiently recent, the NC WW/GW LC Program counts back 6 months (i.e., 180 days) from the date the application is received in our office. Any PT Sample result submitted with an application must be the most recent attempt and have a study close date no earlier than this date.

Laboratories that submit two consecutive Unacceptable PT Sample Results for a Parameter Method while attempting to gain Certification, shall then submit CARs and two consecutive Acceptable PT Sample Results, analyzed within the previous six months, prior to being granted Certification.

***Note:** Initial Certification for multiple analyte parameters will be granted if the PT meets the 80% Rule (see Section 5.3.1). However unacceptable analytes must be reported as "estimated" similarly to Provisional Certification described in Section 5.3.2 until acceptable results are submitted.*

3.2 Certification Maintenance/Renewal

To renew Certification each year, laboratories must have acceptable PT Sample results submitted to the NC WW/GW LC Program, directly from the Accredited PT Sample Provider, for each parameter method (as required by this document) by **September 30**.

NOTE: Even if a laboratory analyzes PT Samples prior to September 30, it does not mean that those samples will be graded and reported to the NC WW/GW LC Program by the September 30 deadline. Laboratories must choose a study that meets all reporting and posting deadlines. Most PT studies are open for 45 days from the day the PTs are shipped to the laboratories. After a study closes, Accredited PT Sample Providers may take up to 30 days to issue reports to participating laboratories and their designated authorities. ***This means, that in order to meet the September 30 deadline, laboratories may need to participate in a PT study that begins no later than Mid-July, unless using “Rapid Response” type samples. It is recommended that laboratories check turn-around times with the proposed PT Sample Provider before ordering.***

The results must be obtained from PT Samples analyzed during the current PT Calendar Year (i.e., January 1 – September 30). The NC WW/GW LC Program will not accept PT Sample results directly from the participant laboratories. When a PT Sample result is not reported by the Accredited PT Sample Provider to this office by the September 30 deadline, the laboratory will be notified in writing (see Attachment 1) and the omission will be counted as a first unacceptable result for that PT Calendar Year. A CAR must be submitted and a remedial PT Sample must be analyzed with a satisfactory result submitted to this office prior to December 31 to maintain Certification for that parameter method.

When two PT Samples for the same parameter method are submitted and analyzed at the same time, an unacceptable result on one or both samples will be considered the first unacceptable result for Certification purposes and a remedial sample must be submitted in accordance with North Carolina Administrative Code, 15A NCAC 2H .0805 (a) (2).

A laboratory that receives an Unacceptable PT Sample Result for a parameter method, or for an individual analyte when multi-analyte parameter PTs are analyzed and greater than 80% are acceptable, must:

- Take steps to identify the root cause of the failure (see Attachment 18 for an example),
- Take corrective action,
- Submit a CAR to this office, and
- Analyze a Remedial PT Sample.

The CAR must include the laboratory's root cause analysis and a copy of any objective evidence (e.g., calibration curves, revised procedures, records, training records, standard operating procedures, etc.) to indicate that the corrective actions have been implemented/completed. The results of the remedial PT Sample and the CAR must be received in this office within 90 days from the date the unacceptable results are issued by the Accredited PT Sample Provider. A laboratory receiving a second (or remedial) Unacceptable PT Sample Result may be Decertified for that parameter method, pursuant to 15A NCAC 2H .0807. At this point, the NC WW/GW LC Program may initiate an assessment of the laboratory's quality control records to determine if reported data has been adversely affected and evaluate if further corrective actions are needed. A laboratory may also be Decertified for failing to provide a CAR pursuant to 15A NCAC 2H .0807 (13). If the remedial PT Sample results are acceptable and an acceptable CAR is received, no further action is necessary.

NOTE: While the NC WW/GW LC Program only requires matrix-specific PT Samples for parameter methods that are matrix-specific, if an unacceptable result is obtained for a specific matrix, the remedial PT Sample must be of the same matrix.

NOTE: Laboratories must report all analytes for multi-analyte group reference sample remedial PTs when less than 80% of the constituent analytes are graded acceptable. Analyzing only a single failed constituent for the analyte group is acceptable only when 80% or greater of the constituent analytes are acceptable. Refer to sections 5.3.1 and 5.3.2 for additional information.

For multi-analyte parameter methods (e.g., organic analyses), when greater than 80% of analytes are acceptable, but one or more individual analytes are graded unacceptable, acceptable performance has been demonstrated for the parameter method. The laboratory must, however, analyze a remedial PT for the individual analytes that were graded unacceptable. **NOTE: If the analyte is not detected in the remedial PT Sample, it must be reported as a “less than” value.** When a remedial PT Sample is graded unacceptable for an individual analyte (constituting a second unacceptable result), the laboratory must qualify data for those individual analytes as “estimated” (whether detected or not) until acceptable results are obtained on two consecutive remedial PT Samples for the analyte in question. Notification will be sent from this office of this single analyte Provisional Certification stating the effective date. The laboratory must complete and return the Provisional Certification Form within 30 days of receipt (see Attachments 15 and 16). Refer to sections 5.3.1 and 5.3.2 for additional information.

3.3 Decertification

A laboratory's receipt of a second consecutive Unacceptable PT Sample Result indicates the corrective action taken earlier by the laboratory was inadequate and may signal major problems with the laboratory's system for testing that analyte or group of analytes. After a second unacceptable result, Decertification of that parameter method for a period of 30 days may be recommended. Further corrective action must be taken by the laboratory and documentation of that action sent to this office for approval before the laboratory can request Recertification. After reviewing the corrective action documentation submitted by a laboratory and prior to remedial PT Sample analyses, an auditor may conduct an on-site inspection/audit of the laboratory, may recommend training for laboratory staff, and/or may recommend that the laboratory obtain third-party assistance in laboratory analytical technique, quality control and instrument operation.

If the results of a PT Sample are not received in this office by September 30, this may be evaluated as a first unacceptable result. If the results of a remedial PT Sample analyzed beyond the September 30 deadline is unsatisfactory (i.e., the September 30 deadline was missed and counted as a first unacceptable result), Decertification for that parameter method may be recommended. A laboratory that reports no PT study results in a calendar year for any parameter method for which it is Certified may be Decertified for that parameter method for a period of up to one year pursuant to 15A NCAC 2H .0807. The laboratory's scope of accreditation found on their CPL will be revised to reflect any Decertifications. A laboratory that reports no PT Sample results in a PT Calendar Year for all parameter methods for which it is Certified may be Decertified for all parameter methods for a period of up to one year. An initial notice of intent to issue a Decertification is sent either electronically or by mail to the laboratory (see example in Attachment 2 for Inorganic Methods and Attachment 3 for Organic Methods). Notices of Decertification with effective dates are sent via certified mail to the laboratory (see example in Attachment 4).

NOTE: Notices of Decertification with effective dates are generally sent within two weeks of the initial notice of intent to issue Decertification; however, the laboratory is encouraged to

take immediate corrective action once a problem has been identified (i.e., as soon as a second consecutive Unacceptable PT Sample Result is received) and immediately suspend analysis or qualify reported values until a contract/subcontract arrangement is made.

All PT Sample results received by the NC WW/GW LC Program will be evaluated according to all evaluation schemes and criteria, as described in this document, regardless of whether or not the PT requirements of the current PT calendar year had been already completed.

A laboratory may appeal a recommended Decertification within 10 business days of receipt of the notice of intent to decertify. This appeal may be made in writing to the NC WW/GW LC Branch Environmental Program Supervisor and/or Water Sciences Section Chief, who will review the case and submit a ruling within one week of the appeal. A laboratory may also appeal a 30-day parameter Decertification any time after issuance of the notice of the effective date of the Decertification. This Decertification appeal may be made to the N.C. Office of Administrative Hearings (<http://www.ncoah.com/hearings/>) in accordance with Chapter 150B of the N.C. General Statutes.

When a laboratory is Decertified for any or all parameter methods, the following conditions shall apply:

- (1) A revised CPL that omits the Decertified parameter method(s) will be issued to the laboratory and will remain effective until Certification is regained. A laboratory shall not analyze, test, measure, or monitor any samples regulated under G.S. 143, Article 21 by the decertified Parameter Method.
- (2) A decertified Commercial Laboratory shall supply written notification of its Decertification to clients that are required to report to the Department of Environmental Quality under G.S. 143, Article 21. Within 30 days of Decertification, the decertified laboratory shall provide the State Laboratory with a list of those clients and copies of the notices sent to each.
- (3) A Commercial Laboratory that has received a Parameter Method Decertification shall supply written notification of the Parameter Method Decertification to clients that are required to report to the Department of Environmental Quality under G.S. 143, Article 21. The laboratory may also make arrangements to supply analysis through another laboratory certified by the State Laboratory for the same Parameter(s) during any Decertification period. Within 30 days of Decertification, the laboratory shall supply the State Laboratory with a list of clients involved, copies of the notices sent to each, and the name and Certification number of the certified laboratory to be used during the Decertification period (see Decertified Laboratory Report form in Attachments 5). Failure to complete and return the supplied form and requested information may result in further enforcement actions (e.g., Decertification – see Attachment 8) pursuant to 15A NCAC 2H .0807 (a) (13).
- (4) A Commercial Laboratory decertified for all Parameters shall not subcontract samples for analyses to other certified laboratories during the Decertification period.
- (5) A Municipal or Industrial Laboratory that has received a Parameter Method Decertification shall have samples requiring that Parameter Method analyzed by another laboratory certified by the State Laboratory for the contracted Parameter Method during any Decertification period. Within 30 days of Decertification, the decertified laboratory shall supply the State Laboratory with the name and Certification number of the certified laboratory to be used during the Decertification period (see Decertified Laboratory Report form in Attachments 6). Failure to complete and return the supplied form and requested information may result in

further enforcement actions (e.g., Decertification – see Attachment 8) pursuant to 15A NCAC 2H .0807 (a) (13).

3.4 Recertification

A laboratory Decertified in accordance with 15A NCAC 2H .0807 (a) may be Recertified at the end of the Decertification period by showing, to the satisfaction of the State Laboratory, that it has corrected the deficiency(ies). Upon approval, a letter with the effective date of the Recertification will be sent from this office (see Attachment 9).

A laboratory Decertified for a parameter method due to unacceptable results on two consecutive PT Samples submitted by an Accredited PT Sample Provider, or on two consecutive split samples may be Recertified after 30 days by reporting acceptable results on two consecutive PT Samples submitted by an Accredited PT Sample Provider in accordance with 15A NCAC 2H .0808 (b). PT Samples may be requested from an Accredited PT Sample Provider at any time during the effective Decertification period; however, Recertification must be requested in writing by completing an Amendment to Laboratory Certification Application found at: <https://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/application-forms>. Select *Amendment to Laboratory Certification Application* in either Word or .pdf format.

NOTE: *In addition to the two consecutive acceptable PT Sample results, an acceptable CAR, a Decertified Laboratory Report, a written request for Recertification and payment of the Recertification invoice are required before Recertification will be issued.*

For Recertification of organic methods that were Decertified for failing the 80% rule on two consecutive PT Sample results, the laboratory must submit two consecutive PT Sample results that pass the 80% rule. Any analytes that are graded as unacceptable in either of the two remedial PT Samples will be given Provisional Certification status until two consecutive PT Samples with acceptable results for those analytes are received.

The study close dates of all testing results submitted with applications for Recertification must have occurred after the dates of the Unacceptable PT Sample Results that prompted the Decertification and within the six months prior to the date of application. When determining whether PT Sample results are sufficiently recent, the NC WW/GW LC Program counts back 6 months (i.e., 180 days) from the date the Recertification application is received in our office. Any PT Sample result submitted with an application for Recertification must have a study close date no earlier than this date.

If a laboratory voluntarily drops Certification to avoid Decertification or if a laboratory has not requested Recertification for a Decertified parameter method after two years, any requests for Certification for that parameter method will be considered as an initial Certification request and the requirements for initial Certification must be met.

3.5 EPA Lab Code

Since different accreditation programs use a wide array of laboratory identification systems, the Accredited PT Sample Providers need a singular means of identifying participant laboratories

when grading and reporting PT Sample results. Therefore, each Certified laboratory must have an EPA Lab Code.

NOTE: The EPA Lab Code is not the same as the NC WW/GW Laboratory Certification Number assigned to each laboratory by the NC WW/GW LC Program or NPDES permit number. Do not report PT results using only the NC WW/GW Laboratory Certification Number or permit number.

The EPA Lab Code assigned to the laboratory performing the analysis must be documented on the results reported to the Accredited PT Sample Provider. Without this EPA Lab Code, the NC WW/GW LC Program may be unable to credit the PT Sample results to the correct laboratory. The EPA contact, for Lab Code assignments for PT studies, is:

Mr. Jeffrey Wilmoth
U.S. EPA Region 4
980 College Station Road

Athens, GA 30605-2720
Email: Wilmoth.Jeffrey@epa.gov
Phone: 706-355-8623

When making the request to the EPA, you must provide the following information:

Contact name	Lab/Facility phone number
Laboratory or Facility Name	Fax number (if available)
Physical Address (with zip code)	Contact individual's e-mail address
PO address (if different)	Type of Study (WP, WS, DMR-QA)

3.6 General PT Analysis and Reporting Requirements

Laboratories are required to analyze an appropriate PT Sample by each parameter method on the laboratory's CPL. The same PT Sample may be analyzed by one or more methods. Laboratories shall conduct the analyses in accordance with their routine testing, calibration and reporting procedures, unless otherwise specified in the instructions supplied by the Accredited PT Sample Provider. This means that they are to be logged in and analyzed using the same staff, sample tracking systems, standard operating procedures including the same equipment, reagents, calibration techniques, analytical methods, preparatory techniques (e.g., digestions, distillations and extractions) and the same quality control acceptance criteria. PT Samples shall not be analyzed with additional quality control. They are not to be replicated beyond what is routine for Compliance Sample analysis. Although, it may be routine to spike Compliance Samples, it is neither required, nor recommended, for PT Samples. PT sample results from multiple analyses (when this is the routine procedure) must be calculated in the same manner as routine Compliance Samples.

As specified in 15 NCAC 2H .0800, in order to meet the minimum standards for Certification, laboratories must use acceptable analytical methods. The acceptable methods are those defined or referenced in the current State and federal regulations for the environmental matrix being tested. All samples, (including PT Samples) that are, or that may, be used for Certification purposes, must be analyzed using approved methods only. All PT Samples are to be analyzed and the results reported in a manner consistent with the routine analysis and reporting requirements of Compliance Samples. Laboratories must document any exceptions. All PT Sample analyses must be recorded in the daily analysis records as for any Compliance Sample. This serves as the permanent laboratory record.

A laboratory must obtain PT Samples from an Accredited PT Sample Provider. A laboratory may use more than one Accredited PT Sample Provider in order to obtain PT Samples for all analytes and methods for which it is Certified or is seeking Certification by the NC WW/GW LC Program. Check your CPL before analyzing and reporting PT Sample results to make sure you are reporting results by all the applicable methods on your CPL. You can report results from several different methods for any given PT Sample. The only limitation is the volume of PT Sample available for analysis. This happens frequently with wet chemistry methods.

NOTE: Free Available Chlorine PT Samples are only available in Water Supply (WS) studies.

A list of methods for which PT Sample analysis is required can be found on the following Laboratory Certification PT Requirements web pages:

Field Laboratory PT Requirements: <http://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/pt-requirements>

Non-Field Laboratory PT Requirements: <http://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/pt-requirements-0>

The laboratory records used to track PT Samples (e.g., chain-of-custody, sample transmittal forms, etc.) can be initiated by laboratory personnel such as the Quality Assurance Officer. PT Samples received as ampules are diluted according to the Accredited PT Sample Provider's instructions. It is important to remember to document the preparation of PT Samples in a traceable log or other traceable format. The diluted PT Sample then becomes a routine Compliance Sample and is added to a routine sample batch for analysis. No documentation is needed for whole volume PT Samples which require no preparation, however the instructions must be maintained.

NOTE: For those laboratories that do not have adequate glassware for PT Sample preparation, and have another lab assist with preparing the PT Sample, it is the participant laboratory's responsibility to retain the PT Sample preparation documentation.

NOTE: Corrective-action PT Samples, which are provided with the true values in a sealed envelope, are not considered PT Samples and do not meet the PT requirements outlined in 15 NCAC 2H .0800. In general, laboratories must not analyze quality control PT Samples of known concentrations with PT Samples, as this would be considered additional quality control and is not the routine testing protocol for Compliance Samples. However, they are recommended when performing troubleshooting prior to analyzing a remedial PT. This would be considered part of the corrective action plan.

Laboratories shall also ensure that, from year to year, PT Samples are equally distributed among personnel trained and qualified for the relevant tests and instrumentation (when more than one instrument is used for routine Compliance Sample analyses), that represents the routine operation of the work group at the time the PT Sample analysis is conducted.

Before the close of a PT study, a laboratory must arrange with the Accredited PT Sample Provider for the study results to be sent **directly from the Accredited PT Sample Provider** to

the North Carolina Wastewater/Groundwater Laboratory Certification Program office before or at the same time that results are released to the laboratory. We cannot accept PT Sample results that are faxed, emailed or mailed from the participant laboratory. The Accredited PT Sample Providers should have the NC WW/GW LC Program office address on file and an area to select this office as a PT Sample report recipient in the data-reporting packet. Contact your Accredited PT Sample Provider if there is any question about this. If you designate our office to receive a report and there was an error on the Accredited PT Sample Provider's part, then we must receive a letter from the Accredited PT Sample Provider identifying the error that occurred. The NC WW/GW LC Program mailing address is as follows:

**NC WW/GW Laboratory Certification Program
Water Sciences Section
1623 Mail Service Center
Raleigh, NC 27699-1623**

Each laboratory must report their EPA Lab Code with the reported data. Each In-State laboratory must report their NC WW/GW Laboratory Certification Number and EPA Lab Code. If this information is not included, the laboratory may not receive proper credit for the PT Sample analyses or may be required to submit an amended report. If you are unsure of your EPA Lab Code, refer to Section 3.5 of this document. If you are unsure of your NC WW/GW Laboratory Certification Number, contact this office at (919) 733-3908. NELAC codes are not required to be reported.

Laboratories must also be careful to designate the correct method code(s) being used for each PT Sample result. To ensure that you are reporting the correct method, review your CPL. If you are using a method that is not listed on your CPL, please contact your auditor so that your CPL can be updated. The reported method code must include the entire method reference as documented on your CPL. For instance, for pH, you must write or enter (when electronic submission of data results is employed) the entire method (e.g., SM 4500H+ B-2011). Writing SM 4500, SM 4500 B, SM 4500 H, 4500 H, or any other incomplete combination is not acceptable. When an Accredited PT Sample Provider utilizes a web-based submittal system, where the laboratory selects the analytical method from a pull-down list, it may be necessary to edit the choices given. Technical difficulties should be addressed with the Accredited PT Sample Provider. You must also indicate the correct revision of a method (e.g., SW-846 8015 C) where listed on your CPL. If an incorrect revision is associated with a PT Sample result, you may receive a letter notifying you that there is a discrepancy and may not receive proper credit for the result. When Certified for multiple methods for a single parameter, results from a single PT Sample analysis may be reported for multiple methods when the same technology is employed and the most stringent QC requirements among the report methods are applied. For example, the result obtained for COD (manual colorimetric) method EPA 410.4, Rev. 2.0, 1993 may be reported for other manual colorimetric methods such as, Standard Methods, 5220 D-2011, Hach 8000 and ASTM D1252-06 B. However, a result must be reported for each Certified method on the laboratory's CPL. Additionally, when merging organics methods (e.g., EPA 600 series and SW-846 8000 series methods) by adhering to the most stringent QC from the two methods, results from a single PT Sample analysis may be reported for the multiple methods. Results must be reported for each method to receive proper credit.

PT Samples must be obtained, analyzed, and reported by each individual laboratory. Individual laboratories are determined by their NC WW/GW Laboratory Certification Number and their

associated CPL. If separate NC WW/GW Laboratory Certification Numbers are issued by the NC WW/GW LC Program, then separate PT Samples are required. It is not acceptable to report one result for any PT Sample for two different laboratories. It is also not acceptable to split a PT Sample between laboratories.

Results must be reported to the Accredited PT Sample Provider prior to the study close date and time using the reporting format specified by the Accredited PT Sample Provider. Any results provided after the close date and time will not be accepted even if the Accredited PT Sample Provider accepts and grades the data. In general, changes to the reported data submitted to the Accredited PT Sample Provider after the study close date will not be accepted for Certification purposes even when the Accredited PT Sample Provider submits an amended report; however, amended reports will be evaluated by the NC WW/GW LC Program on an individual basis. Most Accredited PT Providers make results available shortly after the study close date so that laboratories can grade their own data and order remedial PT Samples as necessary. Prior to the study close date and time, the laboratory shall authorize the Accredited PT Sample Provider to release the laboratory's final evaluation report directly to the NC WW/GW LC Program.

A laboratory must not send or subcontract analysis of any PT Sample, or a portion of a PT Sample, to another laboratory or unassociated entity for any analysis for which it is Certified or seeking Certification unless the practice represents the routine analysis and reporting scheme utilized by the laboratory. Conversely, a lab must not knowingly receive and analyze any PT Sample or portion of a PT Sample from another laboratory for which the results of the PT Sample are intended for use for initial or continued Certification.

A laboratory must not communicate with any other laboratory (including laboratories within the same company) or person regarding the results obtained from the analysis of the PT Sample, before the Accredited PT Sample Provider releases the study results (i.e., prior to the closing date of the study).

A laboratory must not attempt to obtain the assigned value of any PT Sample used to satisfy initial or continued Certification requirements prior to the closing date of the study.

3.7 Parameter-Specific PT Requirements

3.7.1 Total Residual Chlorine (low-level)

For colorimetric procedures, Total Residual Chlorine (TRC) PT Samples must be analyzed on the same spectrophotometric program using the same procedure that is used for routine Compliance Sample analysis. There are two options for achieving this when you have a low-level permit requirement:

1. If a facility having a low-level permit requirement analyzes a regular-level TRC PT Sample, it must be diluted to the verified range of the low-level curve routinely used. The reported result must then be calculated using the dilution factor and the TRC value obtained.
2. Since the dilution factor in option 1 may introduce error, it is recommended that facilities having a low-level permit requirement order and analyze a low-level

TRC PT Sample. This PT Sample should be within the range of your verified curve on the low-level program.

3.7.2 Microbiological Samples

Only quantitative microbiological PT Samples will be accepted for coliform, Enterococci and Salmonella. The results for microbiology PT Samples (i.e., total coliform, fecal coliform, E. coli, Enterococci and Salmonella) must be reported as a number of colonies per 100 mL (CFU/100 mL or MPN/100 mL). This applies to both Membrane Filtration (MF) methods and Most Probable Number (MPN) methods. Microbiology PT Samples for the Water Supply (WS) study are reported as presence/absence and are not acceptable for demonstrating proficiency for the NC WW/GW LC Program.

3.7.3 Biochemical Oxygen Demand (BOD)

Laboratories are reminded that the pH of BOD PT Samples must be adjusted prior to dilution. In order to obtain accurate results for this test, the analysis must be performed at a pH between 6.0 and 8.0. In some Municipal laboratories, adjusting the pH of “real” samples is never required as they always fall in the method-defined range and when PT Samples are analyzed, this step may be overlooked. Accredited PT Sample Providers must prepare the DEMAND concentrate with acid in order to produce a homogenous, stable PT Sample. After the PT Sample is prepared according to manufacturer’s instructions, the pH will still be slightly acidic. If the pH is not adjusted prior to preparing analytical dilutions, there is a significant risk of receiving an unacceptable result. The best way to adjust the pH is to use a dilute solution of sodium hydroxide (~0.2 molar) and add it one drop at a time to the diluted sample, mixing and then checking the pH after each addition until the pH is between 7.0 and 7.2, as required by the approved analytical method.

NOTE: *Luminescence Dissolved Oxygen (LDO) is a separate parameter method technology and requires a separate PT Sample analysis.*

3.7.4 Chlorophyll *a*

Because of the lack of commercially-prepared PT Samples for chlorophyll *a*, NC DWR will conduct chlorophyll *a* round robin studies in the spring or summer of each year, and follow-up studies in the fall as needed, for laboratories Certified for this parameter. NC DWR staff will collect the samples and distribute them to participating laboratories. Participating laboratories analyze these samples at their own expense and will not charge a fee for the analyses. The round robin studies will also include volunteer academic and governmental laboratories to increase the data pool for statistical evaluation purposes. The Division will use the results of the round robin studies to assess laboratory performance and comparability. Laboratories will be notified and given instruction prior to each study. A link to the Chlorophyll *a* Round Robin Study SOP can be found on the NC WW/GW LC website at <http://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch/pt-requirements-0>.

3.8 Matrix-Specific PT Requirements

The NC WW/GW LC Program has opted not to require use of solid or hazardous waste PT Samples for methods that are not matrix-specific to soil analyses. A laboratory may, however, elect to analyze one or more matrices for a given method. When Certified for a method by both aqueous and non-aqueous matrices, a single PT Sample in either matrix shall suffice for demonstration of proficiency for that parameter method. A specific PT Sample matrix is required only in cases where a method is matrix-specific (e.g., SW-846 9071B and SW-846 7471B) or if the laboratory is only certified for one matrix when multiple matrices are available. One exception to this is SW-846 9045D. No PT Sample analysis is required for that method. If Unacceptable PT Sample Results are obtained, remedial PT Samples must represent the same matrix as the Unacceptable PT Sample Result. If the remedial PT Sample result is unacceptable, Decertification may be recommended for the parameter method in any or all matrices, not just the matrix analyzed for those PT Samples. The same principle is applied to Provisional Certifications.

3.9 DMR-QA PT Study Exemption for NC Permittees

In 2008, the NC WW/GW LC Program appealed to the US EPA Clean Water Enforcement Branch, Water Protection Division for permittee exemption from the National Pollution Discharge Elimination System (NPDES) DMR-QA PT program. After a thorough review of the NC WW/GW LC Program, it was deemed that the NCDEQ PT program provides adequate quality assurance to replace EPA's DMR-QA PT study program. Therefore, all NC dischargers; classified as both Major and Minor, are exempt from the DMR-QA PT Study program as of May 13, 2009. NC dischargers will no longer receive DMR-QA PT study reporting packages from EPA. (See Attachment 10 for the EPA letter granting exemption to NC permittees from the DMR-QA PT study). In accordance with this agreement, the NC WW/GW LC Program will submit annual reports (similar to a DMR-QA pass/fail report) to EPA Region 4, which includes the following statistical information with regard to DMR-QA analytes:

- Pass/fail rates for laboratories
- Pass/fail rates for analytes
- Number of laboratories in the NC WW/GW LC Program
- Number of audits conducted

The NC WW/GW LC Program will accept DMR-QA PT Samples for Certification maintenance as long as the results are made available to the NC WW/GW LC by September 30.

If DMR-QA PT Sample results will not be available by September 30, laboratories must purchase PT Samples for another PT study and acceptable results must be reported to NC WW/GW LC Program by September 30.

NOTE: Just because a laboratory analyzes DMR-QA PT Samples prior to September 30, it does not mean that they will be graded and reported to the NC WW/GW LC Program by the September 30 deadline. Laboratories must choose a study that meets all reporting and posting deadlines. After a study closes, Accredited PT Sample Providers may take up to 30 days to issue reports to participating laboratories and their designated authorities. This means, that in order to meet the September 30 deadline, laboratories must participate in a PT study that begins no later than Mid-August, unless using "Rapid Response" type PT Samples which typically cost much more than a routine study.

Not all of the analytes listed on a NPDES permit may be included in the DMR-QA PT study; however, each laboratory must analyze a PT Sample for every parameter method on the CPL, where required, to satisfy NC WW/GW LC Program requirements. Additional PT Samples may need to be ordered. For this reason, and the fact that the WP study reporting procedures are easier and results are generally obtained in a timelier fashion, most labs opt not to continue participation in the DMR-QA PT Study.

Refer to Section 7.0 for additional information on NC WW/GW LC Program auditor oversight and tracking of laboratory participation in the PT process.

4.0 PT Sample Record Retention

The laboratory shall retain all records necessary to facilitate historical reconstruction of the analysis and reporting of analytical results for PT Samples. This means the laboratory must have available and retain for five years [pursuant to 15A NCAC 2H .0805 (a) (7) (E and (g) (1))] all of the raw data, including benchsheets, instrument printouts and calibration data, for all PT Sample analyses and the associated QC analyses conducted by all parameter methods.

These records shall include a copy of the reporting forms used by the laboratory to report the analytical results to the Accredited PT Sample Provider. If the analytical results for the PT Samples were entered or uploaded electronically to an Accredited PT Sample Provider website, the laboratory shall retain a copy of the on-line data entry summary or similar documentation of entry of the PT Sample results from the Accredited PT Sample Provider website.

The laboratory shall make these records available for review upon request by the NC WW/GW LC Program. Auditors will review PT records during on-site evaluations.

5.0 Evaluating and Grading PT Sample Results

Accredited PT Sample Providers are currently being required to follow Volume 3, Section 5.9 of the 2016 TNI Standard for PT Sample results reporting and grading. For Water Pollution (WP) studies, the Accredited PT Sample Providers use the same pooled-result grading system used formally by EPA when determining whether a result is scored “Acceptable” or “Not Acceptable”.

- An “Acceptable” PT Sample result is one where the reported value falls within the acceptance limits.
- A “Not Acceptable” grade is assigned when the submitted PT Sample result falls outside the acceptance limits.

NC will accept the PT Providers’ evaluation with a few exceptions in regard to reported “less than” and “greater than” value results. All “less than” and “greater than” results that are graded as “Not Acceptable”, “Unacceptable”, “Fail”, or any other term used to indicate exceedances of the acceptable limit by the Accredited PT Sample Provider will be reviewed by the NC WW/GW LC Program to determine if the results were reported to levels consistent with the laboratory’s routine reporting limits. If so, the results may be accepted.

The 2016 TNI standard evaluations are listed below:

- 1) Greater-than value reporting (“>”) and scoring of all “>” results: If a laboratory reports results that are qualified with a “>” symbol, those results will be scored as “Not Acceptable” under the 2016 TNI Standard. Please note that this scoring protocol will also be applied to quantitative microbiology results and may conflict with historically acceptable and method-allowable reporting practices, particularly for most probable number (MPN) methods.
- 2) Less-than value reporting (“<”): Similar to the 2003 TNI Standard, there is an emphasis on laboratories being able to quantitate and report down to the TNI Proficiency Testing Reporting Limits (PTRLs). If a laboratory uses a method that is incapable of detecting a PT analyte down to the PTRL, the laboratory risks reporting a false negative result when an analyte is spiked into the PT sample. If the analyte is spiked into a PT sample, a reported result of <PTRL, <LOQ, or a value of “0” will receive an evaluation of “Not Acceptable.”

NC requires laboratories to report analytical results for PT Samples as follows:

For instrument technologies that employ a multi-point calibration, the laboratory shall report the analytical result to the value of the lowest calibration standard established for the test method used to analyze the PT Sample. The working range of the calibration under which the PT Sample is analyzed shall be the same range as used for routine Compliance Samples.

- Any PT Sample result at a concentration above or equal to the lowest calibration standard shall be reported as the resultant value.
- Any PT Sample result at a concentration less than the lowest calibration standard shall be reported as less than (“<”) the value of the lowest calibration standard.

For instrument technologies (e.g., ICP-AES or ICP-MS) that employ standardization with a zero-point and a single-point calibration standard, the laboratory shall evaluate the analytical result to the established practical quantitation limit (this may be a laboratory’s Limit of Quantitation or LOQ) established for the test method used to analyze the PT Sample.

- Any PT Sample result at a concentration above or equal to the PQL shall be reported as the resultant value.
- Any PT Sample result at a concentration less than (“<”) the PQL shall be reported as less than the value of the PQL.

Any test or measurement results that are evaluated as “Not Acceptable”, “Unacceptable”, “Fail”, or any other term used to indicate exceedances of the acceptable limit by the Accredited PT

Sample Provider, and conform to the evaluation of grading as described in this document, will require a CAR and remedial PT Sample analysis as described in the following sections.

Each time the NC WW/GW LC Program receives and evaluates PT Sample results for a laboratory, an electronic or hard copy letter of acknowledgement with the NC WW/GW LC Program's evaluation and instructions for remedial actions, if required, will be sent to the participant laboratory. Examples of these notices can be found in Attachments 11, 12 and 13. These letters may also contain additional optional verbiage.

5.1 Selective Ion Mode (SIM) Analysis

SIM analysis of PT Samples is not required to maintain Certification. However, if it is the routine method of analysis for a particular analyte, then analysis of that analyte utilizing SIM shall be required. PT Samples analyzed using SIM, will be evaluated and graded the same as for any other single-analyte or multi-analyte group as described in Sections 5.0 and 5.2 through 5.7. If unacceptable results are obtained using SIM, remedial PT Samples must also be analyzed using SIM. Remedial PT Sample results will be evaluated and Decertification may be recommended for the parameter method in any or all matrices, not just the matrix analyzed for those PT Samples. The same principle is applied to Provisional Certifications. After two consecutive unacceptable results are obtained for an individual analyte, the laboratory should immediately begin qualifying data as "estimated". Upon receipt of the Provisional Certification notification (sent via certified mail), the laboratory must qualify any reported results for those analytes as "estimated". The laboratory must also complete a Provisional Certification Form (See Attachments 15 and 16), within 30 days of receipt, identifying North Carolina clients for which affected data may be reported. Failure to complete and return this form by the date due may result in further enforcement actions.

5.2 Single-Analyte PT Samples

For single-analyte PT Samples, laboratories must report acceptable results for that analyte.

5.3 Multi-Analyte Group PT Samples

Multi-analyte evaluation applies to the various analyte groups for which Certification is offered by the NC WW/GW LC Program and PT Sample analysis is required. These include:

Purgeable Halocarbons	Nitrosamines	Base/Neutral and Acid Organics
Purgeable Aromatics	Organochlorine Pesticides	Chlorinated Acid Herbicides
Acrolein, Acrylonitrile, Acetonitrile	Polychlorinated Biphenyls	Organophosphorus Pesticides
Organic Phenols	Nitroaromatics and Isophorone	N-Methylcarbamates
Benzidines	Chlorinated Hydrocarbons	Volatile Petroleum Hydrocarbons
Phthalate Esters	Purgeable Organics	

5.3.1 80% Rule

For multi-analyte groups containing five or more analytes, laboratories must report acceptable results for greater than or equal to 80% of each of the individual analytes in the PT Sample for the cumulative result to be evaluated by the NC WW/GW LC Program as acceptable. This is called the "80% Rule." For example, if acceptable results are reported for 9 of 15 Volatile Organic Compounds (VOCs) in a given PT Sample, the

cumulative result is not acceptable because only 60% of the analyte results reported fell within the established acceptance limits. The laboratory needs to report correct results for at least 12 of the 15, or 80%, of the analytes for the result to be considered acceptable. Results for all spiked components from the primary list of the target group specified in the analytical method must be reported. If a component is spiked, and on the primary list of the target group, and the laboratory elects not to report that component, it counts as an individual failure towards the 80% rule.

Alternatively, the laboratory may appeal to report an abbreviated list if they can demonstrate that the abbreviated list is a routine reporting scheme for their NC data reporting. Abbreviated lists must be submitted to this office prior to analyzing the PT sample when reporting an abbreviated list. Conversely, constituents that are not in the primary list of the target group and are reported voluntarily will be counted toward the 80% rule.

It is also important to understand how false positive and false negative results affect the acceptability of multi-analyte group PT Samples:

- A false positive result occurs when a laboratory incorrectly reports an analyte concentration greater than the limit of detection when that analyte is not present in the PT Sample. Each false positive counts as an individual failure towards the 80% rule.
- A false negative result occurs when a laboratory incorrectly reports an analyte concentration less than the limit of detection for an analyte that is actually present in the PT Sample. Each false negative counts as an individual failure towards the 80% rule. Unreported results for analytes present in the PT Sample are also considered false negatives and count as individual failures toward the 80% rule unless reporting of an abbreviated list has been previously approved by the NC WW/GW LC Program.

Determining the overall percentage may become more complicated when these type errors are encountered. Consider the following example:

A laboratory submits PT Sample results for the Base/Neutral and Acid Organics (BNAs) analyte group. The PT Sample contained a total of 40 primary list analytes and the laboratory submitted acceptable results for 35 of the analytes and obtained unacceptable results for 2 analytes. Three spiked analytes were not reported and, therefore, considered false negatives. The laboratory also reported 4 compounds that were not present (i.e., false positives).

The evaluation is determined by the following equation:

$$\begin{aligned}\% \text{ Acceptable} &= [(Total - (Unacceptable + False Negatives + False Positives)) / Total] \times 100\% \\ &= [(40 - (2 + 3 + 4)) / 40] \times 100 \\ &= [(40 - (9)) / 40] \times 100 \\ &= [31 / 40] \times 100 \\ &= 77.5\%\end{aligned}$$

The four false positives, the three false negatives and the two unacceptable results count against the number of acceptable results reported (i.e., 40-9) and since the false positives are not in the PT Sample, they are not added to the total number of analytes (i.e., 40). Since the overall evaluation yielded less than 80%, the laboratory must analyze another PT Sample successfully within 90 days of the report date to maintain Certification for that analyte group.

NOTE: *Analytes not spiked in a PT Sample and appropriately reported as less than (<) values will be counted toward the number of acceptable analytes.*

Laboratories must analyze a remedial PT Sample if they do not attain a score of at least 80%. In this case, the results of all individual analytes detected in the remedial PT Sample must be reported – not just the individual analytes that were graded unacceptable in the first PT Sample.

5.3.2 Individual Analyte Corrective Actions and Provisional Certification

When a score of 80% or better is obtained, but one or more individual analytes are graded unacceptable, the laboratory must successfully analyze a remedial PT Sample for those analytes within 90 days of the report date to demonstrate there is not a systemic problem with the analysis of those specific analytes.

After two consecutive unacceptable results are obtained for an individual analyte, the laboratory should immediately begin qualifying data as “estimated”. Upon receipt of the Provisional Certification notification (sent via certified mail), the laboratory must qualify any reported results for those analytes as “estimated”. The laboratory must also complete a Provisional Certification Form (See Attachments 15 and 16), within 30 days of receipt, identifying North Carolina clients for which affected data may be reported. Failure to complete and return this form by the date due may result in further enforcement actions. The laboratory must then obtain acceptable results on two consecutive PT Samples for the specific analyte in order to remove the Provisional Certification status. Upon approval, a letter with the effective date of rescission of the Provisional Certification status will be sent to the laboratory (see Attachment 17). If the laboratory is unable to obtain acceptable results on two consecutive PT Samples, Decertification for the entire parameter method may be recommended. Failing to report results or to submit a CAR by the date due may result in a recommendation for Decertification for the parameter. If acceptable results are obtained on two consecutive PT Samples, the Provisional Certification status for those analytes will be removed and the PT requirements for that PT Calendar Year will be met. A notification letter with effective dates will be issued by the NC WW/GW LC Program (See Attachment 12 or 13).

5.4 Multiple Concentration Levels

When a PT Sample for a parameter includes multiple ampules, each containing a different concentration level, the results reported for each level are first graded separately using the 80% rule. Once the acceptability of each level has been determined, the >50% Rule is applied to determine the overall acceptability of the results. The >50% Rule requires passing >50% of the different concentration levels to be considered acceptable (i.e., if 2 levels are analyzed, you must

obtain acceptable results on both levels). If the >50% Rule is not satisfied, remedial PT Samples for all analytes in both concentration levels must be submitted.

The acceptability of the overall result is not determined by the average acceptability rate of the multiple levels.

Failing >50% Rule Example – A laboratory submits results for a two-level BNA PT Sample and 92% of the analytes in one PT Sample level are reported correctly, but only 70% of the analytes in the other level are reported correctly. The overall result is unacceptable because only 50% of the individual levels satisfy the 80% rule. The laboratory must analyze remedial PT Samples for all analytes in both concentration levels.

Passing >50% Rule Example – A laboratory submits results for a two-level BNA PT Sample and 92% of the analytes in one PT Sample level are reported correctly, and 80% of the analytes in the other level are reported correctly. The laboratory must analyze remedial PT Samples for only the target analytes that were unacceptable in each concentration level that was unacceptable. For example, if Vinyl Chloride was unacceptable in the low concentration level and Chloroethane was unacceptable in the high concentration level, the remedial for Vinyl Chloride would be analyzed in a low concentration level PT and the remedial for Chloroethane would be analyzed in a high concentration level PT.

NOTE: A remedial PT Sample may or may not contain any or all of the unacceptable target analytes that were in the original PT Sample. This is acceptable.

5.5 Parameter-Specific PT Evaluations

Parameter evaluations that do not follow the schemes detailed in sections 5.2 through 5.4 are described in this section.

- **Extractable Petroleum Hydrocarbons (EPH) and Volatile Petroleum Hydrocarbons (VPH)**

PT Sample analysis is not required for EPH and VPH.

- **1,2-Dibromomethane (EDB)**

To obtain or maintain Certification for the methods used to analyze and report EDB, acceptable results must be obtained for all constituent analytes in the reference method cited. Refer to Table 3 below.

Table 3. EDB Required Analytes

Method	Analytes Required
EPA 504.1	1,2-Dibromoethane (EDB), 1,2-Dibromo-3-Chloropropane (DBCP), 1,2,3- Trichloropropane (123-TCP)
SW-846 8011	1,2-Dibromoethane (EDB),

	1,2-Dibromo-3-Chloropropane (DBCP)
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Some regulatory agencies require reporting of EDB only by EPA 504.1. To report a reduced list for EDB, the laboratory must demonstrate that this is the routine reporting scheme for NC clients and obtain prior approval from this office. Both WP And WS studies will be accepted for EPA Method 504.1.

- **Polychlorinated Biphenyls (PCBs)**

Accredited PT Sample Providers generally spike PCB PT Samples with one or more Aroclors. Acceptable results require proper identification and accurate quantitation of the correct Aroclor(s). In order to evaluate PCB PT Sample results consistently, NC treats them as a single analyte parameter (i.e., any unacceptable result will be considered a parameter miss and require analysis of a remedial PT Sample for the entire parameter). Laboratories must report acceptable results (including “less than” values at the laboratory’s reporting limit) for all Aroclors in order for the cumulative result to be acceptable. Additionally, since specific Aroclors may not be requested from the Accredited PT Sample Provider, a remedial PT Sample may or may not contain any or all of the unacceptable Aroclors that were in the original PT Sample. This is acceptable.

- **Multi-Analyte PTs Containing Less Than or Equal to Four Analytes**

For these multi-analyte groups containing four analytes, laboratories must report acceptable results for 100% of each of the individual analytes in the PT Sample for the cumulative result to be acceptable.

5.6 Matrix-Specific PT Evaluations

Matrix-specific PT Samples are not required for methods with multiple matrix options. When Certified for multiple matrices for a single method, the laboratory may choose which matrix to analyze. If a laboratory chooses to analyze multiple matrices, each matrix (aqueous, non-aqueous and oil) will be evaluated and graded independently as described in Sections 5.0 through 5.5.

If a laboratory, certified for multiple matrices for a single method, chooses to analyze only one matrix, both matrices may be decertified for the parameter method if two consecutive unacceptable results are obtained for the only matrix analyzed.

5.7 Multiple Studies Analyzed at the Same Time

When multiple study results are reported at about the same time, the closing dates of the individual PT studies will be used to determine the sequence of the analytical results. When studies are concurrent, the >50% Rule (see Section 5.4) will be applied.

6.0 Complaint Resolution

The laboratory shall submit questions about PT Samples or evaluations made by the Accredited PT Sample Provider to the Accredited PT Sample Provider. If the Accredited PT Sample Provider is not able or is unwilling to resolve the question to the satisfaction of the laboratory, the laboratory shall refer those questions to the PT Sample Provider’s Accreditor.

7.0 Auditor Oversight and Tracking

Certified laboratories and laboratories seeking Certification are assigned to an auditor, in general, by region. Each auditor is assigned to the laboratories in one or more of the following regions:

- | | | |
|-----------------------|---------------------|------------------------|
| • Asheville Region | • Raleigh Region | • Winston-Salem Region |
| • Fayetteville Region | • Washington Region | • Washington Region |
| • Mooresville Region | • Wilmington Region | • Out-of-state Labs |

The auditors are responsible for tracking and evaluating the PT Sample analyses and results for each of their assigned laboratories to verify that the requirements of 15 NCAC 2H .0800 and this document are adequately satisfied. This is accomplished through a PT tracking system, which is maintained by each auditor for the laboratories they track. The tracking system contains all the methods that a laboratory is Certified for and tracks associated PT Sample results, CARs, evaluation letters and any applicable Decertification, Recertification and Provisional Certifications. The tracking systems maintained by each auditor are also independently assessed for accuracy and completeness.

The auditors are responsible for ensuring:

- Each laboratory has an assigned EPA Lab Code.
- PT Samples are entered into the laboratory sample receipt log as samples and are tracked through the laboratory as routine Compliance Samples.
- Each laboratory has successfully analyzed a PT Sample for each parameter method on their CPL, where a PT Sample is required. If the laboratory has not met that requirement, then the assigned auditor shall notify the laboratory. The auditor will not recommend initial Certification for parameter methods for which the laboratory has not completed satisfactory PT Sample analyses within the last six months.
- Each laboratory's PT Sample results are reported directly from the Accredited PT Sample Provider to this office by the September 30 deadline.
- Each laboratory reported PT Sample results to the Accredited PT Sample Provider prior to the closing date or deadline issued by the Accredited PT Sample Provider.
- Each laboratory takes corrective action for any unacceptable results. The auditor is also responsible for providing technical assistance during troubleshooting when asked or as deemed necessary. This may involve initiating an on-site inspection of the laboratory facilities or records.
- Remedial PT Sample results are received in this office within 90 days of the date the unacceptable results report was issued.
- Recommending Decertification or Provisional Certification (depending upon the circumstances), any time the requirements of 15 NCAC 2H .0800 or this document are not met and ensuring the analyses are contracted to or performed by a Certified laboratory.
- Each laboratory successfully analyzes two consecutive PT Samples for a particular parameter method before Recertification for a Decertified parameter method is issued.
- PT data is reviewed during on-site inspections to check compliance with the requirements outlined in 15 NCAC 2H .0800 and this document (e.g., appropriately analyzed and documented, appropriately qualified when under Provisional Certification status, appropriately subcontracted when Decertified, Proficiency, etc.). Refer to Attachment 19

the Proficiency Testing (PT) Checklist for Non-Field Laboratories and Attachment 20 for the Proficiency Testing (PT) Checklist for Field Laboratories.

- PT Sample results are entered into a central PT tracking spreadsheet.

Chemist IIs are responsible for directing and supervising the monitoring of each Certified laboratory's analysis of PT Samples for all Certified parameter methods. Auditor recommendations for method Decertifications are evaluated by the Chemist IIs for recommendation to the Environmental Program Supervisor II.

The Environmental Program Supervisor II has delegated authority to issue Decertification and Recertification. The Environmental Program Supervisor II is also responsible for preparing and submitting an annual report (similar to a DMR-QA pass/fail report) to EPA Region 4, which includes the statistical information listed in Section 3.9 of this document.

This document and subsequent revisions will be posted on the Laboratory Certification website at <http://deq.nc.gov/about/divisions/water-resources/water-resources-data/water-sciences-home-page/laboratory-certification-branch>. Hard copies may be requested from this office. At the beginning of each PT Calendar Year, a memorandum will be sent to each Certified laboratory detailing any changes to this document or the PT requirements pertinent to the NC WW/GW LC Program. The memorandum may be sent to Certified laboratories in either electronic (for laboratories that have an email address on file) or hard copy (for laboratories that do not have an email address on file) format.

8.0 References

- 8.1** North Carolina Administrative Code Title 15, Department of Environment and Natural Resources Chapter 2, Environmental Management Division, Subchapter 2H, Procedures for Permits, Approvals, Section .0800 Laboratory Certification.
- 8.2** United States Code of Federal Regulations. Title 40 Chapter I. Subchapter D. Part 136 *et. Seq.* Guidelines Establishing Test Procedures for the Analysis of Pollutants. U.S. Government Printing Office. Washington, D.C.
- 8.3** US EPA NERL-Ci-0045 "National Standards for Water Proficiency Testing Studies, Criteria Document," December 30, 1998.

9.0 Revision History

Revision Number	Date Revised	Revision Summary
1.0	01/18/2011	Section 4.2.1, pg. 24 – An error in the example PT evaluation was corrected. The equation was changed to %Acceptable = $[(35-6)/40] \times 100\% = 72.5\%$ and "false negative" was corrected to read "false positive".
1.1	02/14/2011	Sections 2.2.1, pg. 5 and 2.4.1, pg. 7 – Added false positives and false negatives to the definitions of Not Acceptable and Unacceptable. Section 2.3.1, pg. 6 – It was found that some Quick Response PT

		<p>Samples have deadlines for reporting, so this was removed from the definition.</p> <p>Section 3.4, pg. 15 – Added the requirements for recertification when a lab voluntarily drops certification to avoid decertification.</p> <p>Section 3.6, pg. 17 – Omitted the reference to matrix-matched samples since this is covered two paragraphs preceding which states that PT samples must be analyzed in the same manner as routine environmental samples.</p> <p>Section 4.2.1, pg. 24 – An error in the example PT evaluation was corrected with input from EPA Region 4. The equation was changed to % Acceptable = $[(40-9)/40] \times 100\% = 77.5\%$</p> <p>Attachments 7 and 18 were added and the remaining attachments appropriately renumbered.</p>
1.2	02/20/2012	<p>Sections 1.0, pg. 3; 2.3 pg. 4; 2.21 pg. 5; 3.1, pg. 10 – ACLASS was added as an approved PT Provider Accreditor.</p> <p>Section 2.10, pg. 4 – A definition of Corrective Action Report (CAR) was added.</p> <p>Section 2.27, pg. 6 – The PT Calendar Year was redefined as January 1 to September 30, moving the PT deadline up one month to accommodate the 90-day remedial PT deadline.</p> <p>Sections 2.33, pg. 7; 3.2, pg. 13; 3.3, pg. 14; 3.8, pg. 22; 6.0, pg. 30 – All references to the initial PT deadline were changed from October 31 to September 30.</p> <p>Section 3.2, pg. 13; 4.2.1, pg. 26; 4.2.2, pg. 26 – The remedial PT deadline was changed from 60 to 90 days.</p> <p>Section 3.3, pg. 15 – Added that labs must take immediate corrective action (in the form of qualifying data results, suspending analysis, etc.) once it is known a second PT failure has occurred and not wait for the provisional or decertification effective date.</p> <p>Section 3.6, pg. 18 – For those laboratories that do not have adequate glassware for PT sample preparation, and have another lab assist with making up the PT sample, it is the participant laboratory's responsibility to retain the PT sample preparation documentation.</p> <p>Section 3.6, pg. 18 – Decertification and provisional certifications will be issued for the parameter method technology, not just the matrix of the PT failed.</p> <p>Section 3.7, pg. 22 – The website address for the Chlorophyll <i>a</i> Round Robin Study SOP was added.</p> <p>Section 3.9, pg. 23 – Added 2009 TNI Standard PT grading requirement.</p> <p>Section 4.2.2, pg. 27 – Added 30-day deadline for Provisional Certification Form.</p> <p>Section 4.4, pg. 28 – Added reference to Section 4.2.2 guidelines to TCLP Metals section.</p>

		<p>Section 6.0, pg. 30 – Added reference to the <i>Proficiency Testing Checklist</i> and the <i>Field Parameter On-site Inspection Checklist</i>.</p> <p>Attachments 1, 2, 3, 7, 8, 10, 11, 12, 13, 14 and 16 were updated to the new deadline requirements and new DWQ Director.</p> <p>Attachment 17 was updated to include a description of the Corrective Action Report and an example Corrective Action Report Form.</p> <p>Attachments 19 and 20 were added.</p>
2.0	02/21/2016	Minor non-substantive editorial changes such as capitalizations, web link updates and document header and department name changes were made throughout the document.
2.0	02/21/2016	Uses of the term “environmental sample” were changed to “Compliance Sample” to better reflect the type of sample for which PT samples analyses are intended to be a measure of.
2.0	02/21/2016	Updated the Table of Contents
2.0	02/21/2016	Updated Attachments to reflect current letters
2.0	05/05/2017	<p>Section 2, pgs. 5-8 – Definitions were added for Certified Parameters Listing, Compliance Sample, NC WW/GW Laboratory Certification Number, Non-Field Laboratory, Proficiency Testing Provider, Proficiency Testing Provider Accreditor (PTPA) and Recertification and sub-section numbers adjusted accordingly.</p> <p>The definition for Proficiency Testing (PT) Provider was combined with the definition for Accredited Proficiency Testing (PT) Provider and then deleted.</p>
2.0	05/05/2017	<p>Section 3.0, pg. 9 – Language stating that Water Supply studies will not be accepted for organic methods was added.</p> <p>Language stating that ready-use type PTs will not be accepted and that SOPs must address how low-level and high-level PTs, including preparation of multiple dilutions of the sample, will be analyzed.</p>
2.0	05/05/2017	Section 3.1, pg. 11 – The following language was added: A specific PT Sample matrix is required in cases where a method is matrix-specific (e.g., SW-846 9071B and SW-846 7471B) and/or when requesting only one matrix when two are available. The exception to this is SW-846 Method 9045D. A PT for that method is not required.
2.0	05/05/2017	Section 3.1, pg. 11 – The following language was deleted: A laboratory must submit an amendment application each time it wishes to become certified for an additional parameter method technology, even if it is already currently certified for other parameter and/or parameter method technologies. Parameters for which certification may be requested are excerpted from 15A NCAC 2H .0804 below.

2.0	05/05/2017	Section 3.1, pg. 11 – Sub-sections (a), (b), (c) and (d) were deleted.
2.0	05/05/2017	Section 3.2, pg. 11 – Section title changed from “Maintenance/Renewal” to “Certification Maintenance/ Renewal”. Because the submission of PT Sample results directly from the Accredited PT Sample Provider is a requirement and the word “encouraged” did not convey that and because the preceding sentence was revised to make that clear, the following sentence was deleted: Laboratories are encouraged to have these results reported directly by the PT provider to the NC WW/GW LC Program by early September to avoid delays in processing the renewal of their Certification.
2.0	05/05/2017	Section 3.3, pg. 13 – The following language was added: All PT Sample results received by the NC WW/GW LC Program will be evaluated according to all evaluation schemes and criteria, as described in this document, regardless of whether or not the PT requirements of the current PT Calendar Year had been already completed.
2.0	05/05/2017	Section 3.4, pg. 15 – The following language was added: For Recertification of organic methods that were Decertified for failing the 80% rule on two consecutive PT results, the laboratory must submit two consecutive PT results that pass the 80% rule. Any analytes that are graded as unacceptable in either of the two remedial PT Samples will be given Provisional Certification status until two consecutive PT Samples with acceptable grades results for those analytes are received.
2.0	05/05/2017	Section 3.5, pg. 15 – The EPA Lab Code contact information was updated to reflect the replacement of Mr. Charles Feldman with Mr. Jeffrey Wilmoth.
2.0	05/05/2017	Section 3.6, pg. 16 – Language was added and deleted to require that a PT Sample be analyzed for each applicable parameter method on the laboratory’s CPL instead of one PT Sample for each parameter technology. Language stating that the spiking of PT Samples was neither required, nor recommended, was also added.
2.0	05/05/2017	Section 3.6, pg. 17 – Language was added to clarify that the requirement to equally distribute PT Samples among trained personnel was on a year to year basis.
2.0	05/05/2017	Section 3.6, pg. 18 – Language was added to clarify that when results from a single PT Sample are reported for multiple methods of the same technology, the most stringent QC requirements among the report methods must have been applied.
2.0	05/05/2017	Section 3.7.3, pg. 20 – The pH adjustment range language was changed from “between 6.5 and 7.5” to “between 7.0 and 7.2” to reflect current requirements.

2.0	05/05/2017	Section 3.7.4, pg. 20 – Language was added to state that chlorophyll <i>a</i> round robin studies may be conducted during the summer. Language was also added to clarify that NC DWR staff would collect and distribute samples and that laboratories will analyze the samples at their own expense and not charge a fee for the analyses.
2.0	05/05/2017	Section 3.8, pg. 20 – The Section name was changed from “DMR-QA PT Study Exemption for NC Permittees” to “Matrix-Specific PT Requirements” and the following language was added: The NC WW/GW LC Program has opted not to require use of solid or hazardous waste PTs PT Samples for methods that are not matrix-specific to soil analyses. A laboratory may, however, elect to analyze one or more matrices for a given method. When Certified for a method by both aqueous and non-aqueous matrices, a single PT Sample in either matrix shall suffice for demonstration of proficiency for that parameter method. A specific PT Sample matrix is required only in cases where a method is matrix-specific (e.g., SW-846 9071B and SW-846 7471B) or if the laboratory is only certified for one matrix when multiple matrices are available. One exception to this is SW-846 9045D. No PT Sample analysis is required for that method. If Unacceptable PT Sample Results are obtained, remedial PT Samples must represent the same matrix as the unacceptably graded failed PT Sample. If the remedial PT Sample result is unacceptable, Decertification may be recommended for the parameter method in any or all matrices, not just the matrix analyzed for those PT Samples. The same principle is applied to Provisional Certifications.
2.0	05/05/2017	Section 3.9, pg. 20 – This Section was labeled as Section 3.8 in the previous Revision.
2.0	05/05/2017	Section 4.0, pg. 21 – This Section was labeled as Section 3.9 in the previous Revision.
2.0	05/05/2017	Section 5.0, pg. 22 – This Section was labeled as Section 4.0 in the previous Revision.
2.0	05/05/2017	Section 5.1, pg. 23 – The following language was added: SIM analysis of PT Samples is not required to maintain Certification. However, if PT Samples are analyzed using SIM, they will be evaluated and graded the same as for any other single-analyte or multi-analyte group as described in Sections 5.0 and 5.2 through 5.7. If unacceptable results are obtained, remedial PT Samples must also be analyzed using SIM. Remedial PT Sample results will be evaluated and Decertification may be recommended for the parameter method in any or all matrices, not just the matrix analyzed for those PT samples. The same principle is applied to Provisional Certifications. After two consecutive unacceptable results are obtained for an individual analyte, the laboratory should immediately begin qualifying data as “estimated”. Upon

		receipt of the Provisional Certification notification (sent via certified mail), the laboratory must qualify any reported results for those analytes as “estimated”. The laboratory must also complete a Provisional Certification Form (See Attachments 15 and 16), within 30 days of receipt, identifying North Carolina clients for which affected data may be reported. Failure to complete and return this form by the date due may result in further enforcement actions.
2.0	05/05/2017	Section 5.2, pg. 23 – This Section was labeled as Section 4.1 in the previous Revision.
2.0	05/05/2017	Section 5.3, pg. 23 – This section was labeled as Section 4.2 in the previous Revision.
2.0	05/05/2017	Section 5.3, pg. 23 – The following parameters were removed from the list of parameters for which PTs are required: TCLP Metals, TCLP Organics, Nonhalogenated Volatile Organics, Extractable Petroleum Hydrocarbons Volatile Extractable Hydrocarbons. While PTs for these parameters are available, they do not reflect the way Compliance Samples are analyzed in practice and not required to obtain or maintain Certification.
2.0	05/05/2017	Section 5.3.1, pg. 24 – Section was labeled as Section 4.2.1 in the previous Revision.
2.0	05/05/2017	Section 5.3.1, pg. 24 – Language was added to clarify the target group of analytes is specified within the analytical method.
2.0	05/05/2017	Section 5.3.2, pg. 25 – Section was labeled as Section 4.2.2 in the previous Revision.
2.0	05/05/2017	Section 5.4, pg. 26 – Section was labeled as Section 4.3 in the previous Revision.
2.0	05/05/2017	Section 5.4, pg. 26 – The section title was changed from “Multiple Matrices and Concentration Levels” to “Multiple Concentration Levels”. All language pertaining to matrices was removed. Matrix-Specific PT Sample evaluations are now addressed in Section 5.6.
2.0	05/05/2017	Section 5.5, pg. 26 – Section was labeled as Section 4.4 in the previous Revision.
2.0	05/05/2017	Section 5.5, pg. 26 – Language was changed to state that PT Samples are not required for TCLP, EPH and VPH.
2.0	05/05/2017	Section 5.5, pg. 27 – The following language concerning Polychlorinated Biphenyls (PCBs) was added: Accredited PT providers generally spike PCB PT Samples with one or more Arochlors. Acceptable results require proper identification and accurate quantitation of the correct Arochlor(s). In order to evaluate PCB PT results consistently, NC treats them as a single analyte parameter (i.e., any unacceptable result will be considered a parameter miss). Laboratories must report acceptable results (including “less than” values) for all Arochlors in order for the cumulative result to be acceptable. Additionally, since specific

		Arochlors may not be requested from the Accredited PT Provider, a remedial PT Sample may or may not contain any or all of the unacceptable Arochlors that were in the original PT Sample. This is acceptable.
2.0	05/05/2017	<p>Section 5.6, pg. 27 – The following language was added: Matrix-specific PT Samples are not required for methods with multiple matrix options. When Certified for multiple matrices for a single method, the laboratory may choose which matrix to analyze. If a laboratory chooses to analyze multiple matrices, each matrix (aqueous, non-aqueous and oil) will be evaluated and graded independently as described in Sections 5.0 through 5.5.</p> <p>If a laboratory, certified for multiple matrices for a single method, chooses to analyze only one matrix, both matrices may be decertified for the parameter method if two consecutive unacceptable results are obtained for the only matrix analyzed.</p>
2.0	05/05/2017	Section 5.7, pg. 27 – Section was labeled as Section 4.5 in the previous Revision.
2.0	05/05/2017	Section 6.0, pg. 27 – Section was labeled as Section 5.0 in the previous Revision.
2.0	05/05/2017	Section 7.0, pg. 28 – Section was labeled as Section 6.0 in the previous Revision.
2.0	05/05/2017	Section 7.0, pg. 28 – The following language was added to describe how auditor oversight and tracking is performed: This is accomplished through a PT tracking system, which is maintained by each auditor for the laboratories they track. The tracking system contains the all the methods that a laboratory is Certified for and tracks associated PT Sample results, CARs, evaluation letters and any applicable Decertification, Recertification and Provisional Certifications. The tracking systems maintained by each auditor are also independently assessed for accuracy and completeness.
3	10/29/18	Title Page – Updated header and footer.
3	10/29/18	Section 3.0, Pg. 9 – Added clarification that WS studies would be accepted for EPA method 504.1.
3	10/29/18	Section 3.1, Pg. 11 – The following language was added for clarification: If a laboratory submits two unacceptable PT Sample results while attempting to gain Certification, two consecutive acceptable PT Sample results and CARs shall then be required prior to being granted Certification.
3	10/29/18	Section 3.6, Pg. 17 – Language was added to the second Note to clarify that the analysis of quality control PT Samples of known concentrations at the same time as PT Samples, is considered additional quality control and not allowed.
3	10/29/18	Section 5.4, Pg. 26 – Examples were added to clarify the

		application of the > 50% rule.
3	10/29/18	Section 5.5, Pg. 27 – The following language was added for clarification: Both WP And WS studies will be accepted for EPA Method 504.1.
3	10/29/18	Section 5.6, Pg. 27 – In the following sentence, the word “both” was changed to “all”: If a laboratory, certified for multiple matrices for a single method, chooses to analyze only one matrix, both matrices may be decertified for the parameter method if two consecutive unacceptable results are obtained for the only matrix analyzed.
4	11/26/19	The spelling of Aroclor was corrected throughout the document.
4	11/26/19	All references to 60-day decertification period were changed to 30-day decertification period to coincide with NC Administrative Code 15 NCAC 2H .0800.
4	11/26/19	Section 2.8, Pg. 5 – The term “supporting documentation” was changed to “Supporting Records” and the term was added to the definitions section to coincide with NC Administrative Code 15 NCAC 2H .0800.
4	11/26/19	Section 2.14, Pg. 6 – The following language was added to the end of the last sentence: “... but must meet all other requirements of this document”.
4	11/26/19	Section 2.27, Pg. 7 – The following definition was inserted here, and subsequent sections were re-numbered: Parameter: Analyte, element, compound, or property being measured.
4	11/26/19	Section 2.28, Pg. 7 – The following definition was deleted: Parameter Method Technology: A type of analytical technology used to measure a parameter which is significantly different from other analytical technologies used to measure the same parameter.
4	11/26/19	Section 2.28, Pg. 7 – The following definition was added: Parameter Method: A type of analytical technique, including materials and tools, used to measure a parameter.
4	11/26/19	Section 2.33 (previously 2.32), Pg. 8 – The following language was deleted: “PT Samples are standards whose true value concentrations are unknown to the laboratory and are supplied by an Accredited PT Sample Provider”.
4	11/26/19	Section 2.33 (previously 2.32), Pg. 8 – The following language was added: “A performance evaluation sample whose true value is unknown to the laboratory and provided by a State Laboratory-approved Vendor to test whether the laboratory can produce analytical results within the specified acceptance criteria”.
4	11/26/19	Section 2.43 (previously 2.42), Pg. 9 – The following language was deleted: “A split sample is one that has been equally divided into two or more sub-samples. Split samples are submitted to different analysts or laboratories and are used to measure the precision of the measurement of a given target analyte or group of analytes and/or relative performance of the participating entities”.

4	11/26/19	Section 2.43 (previously 2.42), Pg. 9 – The following language was added: “A Split Sample is two or more representative portions taken from a sample or subsample and analyzed by two or more laboratories approved by the State Laboratory and are used to measure the precision of the measurement of a given target analyte or group of analytes and/or relative performance of the participating entities”.
4	11/26/19	Section 2.45, Pg. 9 – The following language was deleted: “The Water Sciences Section of the North Carolina Division of Water Resources, or its successor”.
4	11/26/19	Section 2.45, Pg. 9 – The following language was added: “The Water Sciences Section, including the Laboratory Certification Branch of the North Carolina Division of Water Resources, or its successor”.
4	11/26/19	Section 2.48, Pg. 9 – The following language was added: “ Supporting Record: Any document or other source of information compiled, recorded, or stored in written form, by electronic process, or in any other manner that provides any information necessary to reconstruct or characterize a reported value”.
4	11/26/19	Section 2.49, Pg. 9 – The following language was deleted: “A PT Sample Result evaluation that exceeds the specified acceptable range as indicated by an Accredited PT Sample Provider, as well as, any false positive or false negative results”.
4	11/26/19	Section 2.49, Pg. 9 – The following language was added: “Those results on Proficiency Testing Samples that do not fall within the Vendor-specified acceptable range as stated by a State Laboratory-approved Vendor, or Split Samples that do not fall within the specified acceptable range as indicated by the State Laboratory, or a failure to meet a reporting deadline imposed by the Vendor or State Laboratory”.
4	11/26/19	Section 2.50, Pg. 9 – The following language was deleted: “supporting documentation”.
4	11/26/19	Section 2.50, Pg. 9 – The following language was added: “Supporting Records”.
4	11/26/19	Section 2.51, Pg. 9 – The following language was added: “ Vendor: An accredited Proficiency Testing Sample provider recognized by The NELAC Institute (TNI). See also Section 2.3, Accredited Proficiency Testing (PT) Sample Provider”.
4	11/26/19	Section 3.0, Pg. 11 – The following language was deleted: “ NOTE: <i>Standard Operating Procedures are not currently required for Field Laboratories; however, they are recommended</i> ”.
4	11/26/19	Section 3.1, Pg. 11 – The following language was deleted: “Any PT Sample result submitted with an application must have a study close date no earlier than this date.
4	11/26/19	Section 3.1, Pg. 11 – The following language was added: “Any

		PT Sample result submitted with an application must be the most recent attempt and have a study close date no earlier than this date”.
4	11/26/19	Section 3.1, Pg. 11 – The following language was deleted: “If a laboratory submits two Unacceptable PT Sample Results while attempting to gain Certification, two consecutive Acceptable PT Sample Results and CARs shall then be required prior to being granted Certification”.
4	11/26/19	Section 3.1, Pg. 11 – The following language was added: “Laboratories that submit two consecutive Unacceptable PT Sample Results for a particular Parameter Method while attempting to gain Certification, shall then submit CARs and two consecutive Acceptable PT Sample Results, analyzed within the previous six months, prior to being granted Certification”.
4	11/26/19	Section 3.2, Pg. 12 – The following language was deleted: “ <i>This means, that in order to meet the September 30 deadline, laboratories should participate in a PT study that begins no later than Mid-July, unless using “Rapid Response” type samples</i> ”.
4	11/26/19	Section 3.2, Pg. 12 – The following language was added: “ <i>This means, that in order to meet the September 30 deadline, laboratories may need to participate in a PT study that begins no later than Mid-July, unless using “Rapid Response” type samples. It is recommended that laboratories check turn-around times with the proposed PT Sample Provider before ordering</i> ”.
4	11/26/19	Section 3.2, Pg. 12 – The following language was deleted: “When two PT Samples for the same parameter method are submitted and analyzed at the same time, an unacceptable result on one or both samples will be considered the first unacceptable result for Certification purposes and a remedial sample must be submitted in accordance with 15A NCAC 2H .0805 (a) (2) (B)”.
4	11/26/19	Section 3.2, Pg. 12 – The following language was added: “When two PT Samples for the same parameter method are submitted and analyzed at the same time, an unacceptable result on one or both samples will be considered the first unacceptable result for Certification purposes and a remedial sample must be submitted in accordance with North Carolina Administrative Code, 15A NCAC 2H .0805 (a) (2)”.
4	11/26/19	Section 3.2, Pg. 12 – The following language was deleted: “Participate in a second PT meeting the criteria listed previously in this policy ”.
4	11/26/19	Section 3.2, Pg. 12 – The following language was added: “Analyze a remedial PT Sample”.
4	11/26/19	Section 3.3, Pg. 14 – The following language was deleted: “When a laboratory is Decertified for any or all parameter methods, the laboratory is required to report certain information to this office within 30 days of the effective date of the 60-day Decertification

		<p>period. This includes the clients for whom State required monitoring analyses are performed, a copy of the notification of Decertification sent to clients, and the Certified laboratory to be used (see Decertified Laboratory Report forms in Attachments 5 and 6). Failure to complete and return the supplied form and requested information may result in further enforcement actions (e.g., Decertification – see Attachment 8) pursuant to 15A NCAC 2H .0807 (a) (13).</p> <p>No testing for the revoked parameter method shall be performed by the laboratory for permittees, clients or wastewater treatment plants reporting to this Department for purposes of State water, wastewater, or groundwater monitoring required under Article 21 of G.S. 143.</p> <p>A revised CPL that omits the Decertified parameter method(s) will be issued to the laboratory and will remain effective until Certification is regained.</p> <p>A Commercial Laboratory Decertified for all parameters cannot subcontract samples for analyses to other Certified laboratories during the Decertification period pursuant to 15A NCAC 2H .0807 I (1) through (4)”.</p>
4	11/26/19	<p>Section 3.3, Pg. 14 – The following language was added: “When a laboratory is Decertified for any or all parameter methods, the following conditions shall apply:</p> <p>(1) A revised CPL that omits the Decertified parameter method(s) will be issued to the laboratory and will remain effective until Certification is regained. A laboratory shall not analyze, test, measure, or monitor any samples regulated under G.S. 143, Article 21 by the decertified Parameter Method.</p> <p>(2) A decertified Commercial Laboratory shall supply written notification of its Decertification to clients that are required to report to the Department of Environmental Quality under G.S. 143, Article 21. Within 30 days of Decertification, the decertified laboratory shall provide the State Laboratory with a list of those clients and copies of the notices sent to each.</p> <p>(3) A Commercial Laboratory that has received a Parameter Method Decertification shall supply written notification of the Parameter Method Decertification to clients that are required to report to the Department of Environmental Quality under G.S. 143, Article 21. The laboratory may also make arrangements to supply analysis through another laboratory certified by the State Laboratory for the same Parameter(s) during any Decertification period. Within 30 days of Decertification, the laboratory shall supply the State Laboratory with a list of clients involved, copies of the notices sent to each, and the name and Certification number of the certified laboratory to be used during the Decertification period (see Decertified Laboratory Report form in Attachments 5).</p>

		<p>Failure to complete and return the supplied form and requested information may result in further enforcement actions (e.g., Decertification – see Attachment 8) pursuant to 15A NCAC 2H .0807 (a) (13).</p> <p>(4) A Commercial Laboratory decertified for all Parameters shall not subcontract samples for analyses to other certified laboratories during the Decertification period.</p> <p>(5) A Municipal or Industrial Laboratory that has received a Parameter Method Decertification shall have samples requiring that Parameter Method analyzed by another laboratory certified by the State Laboratory for the contracted Parameter Method during any Decertification period. Within 30 days of Decertification, the decertified laboratory shall supply the State Laboratory with the name and Certification number of the certified laboratory to be used during the Decertification period (see Decertified Laboratory Report form in Attachments 6). Failure to complete and return the supplied form and requested information may result in further enforcement actions (e.g., Decertification – see Attachment 8) pursuant to 15A NCAC 2H .0807 (a) (13)."</p>
4	11/26/19	<p>Section 3.4, Pg. 15 – The following language was deleted: "NOTE: In addition to the two consecutive acceptable PT Sample results, an acceptable CAR, a Decertified Laboratory Report and payment of the Recertification invoice are required before Recertification will be issued".</p>
4	11/26/19	<p>Section 3.4, Pg. 15 – The following language was added: "NOTE: In addition to the two consecutive acceptable PT Sample results, an acceptable CAR, a Decertified Laboratory Report, a written request for Recertification and payment of the Recertification invoice are required before Recertification will be issued".</p>
4	11/26/19	<p>Section 3.4, Pg. 15 – The following language was deleted: "After two years, if a laboratory has not requested Recertification for a Decertified parameter method or if a laboratory voluntarily drops Certification to avoid a Decertification, any requests for Certification for that parameter method will be considered as an initial Certification request and the requirements for initial Certification must be met".</p>
4	11/26/19	<p>Section 3.4, Pg. 15 – The following language was added: "If a laboratory voluntarily drops Certification to avoid Decertification or if a laboratory has not requested Recertification for a Decertified parameter method after two years, any requests for Certification for that parameter method will be considered as an initial Certification request and the requirements for initial Certification must be met".</p>
4	11/26/19	<p>Section 3.5, Pg. 17 – The following language was added: "When making the request to the EPA, you must provide the following information:</p>

		<p>Contact name</p> <p>Laboratory or Facility Name</p> <p>Physical Address (with zip code)</p> <p>PO address (if different)</p> <p>Lab/Facility phone number</p> <p>Fax number (if available)</p> <p>Contact individual's e-mail address</p> <p>Type of Study (WP, WS, DMR-QA)</p>
4	11/26/19	Section 3.6, Pg. 17 – The following language was added: “NOTE: Free Available Chlorine PT Samples are only available in Water Supply (WS) studies”.
4	11/26/19	Section 3.6, Pg. 17 – The following language was deleted: “No documentation is needed for whole volume PT Samples which require no preparation (e.g., pH), but it is recommended that the instructions be maintained”.
4	11/26/19	Section 3.6, Pg. 17 – The following language was added: “No documentation is needed for whole volume PT Samples which require no preparation, however the instructions must be maintained”.
4	11/26/19	Section 3.6, Pg. 18 – The following language was deleted: “In cases where there is more than one laboratory in your network (e.g., corporate organizations, multiple permitted facilities, etc.), each laboratory must be treated independently”.
4	11/26/19	Section 3.6, Pg. 19 – The following language was deleted: “If you work at two locations, you must analyze one PT Sample at the first location using all the equipment and reagents at the first location. You must then order and analyze another PT Sample at the second location using the equipment and reagents at the second location”.
4	11/26/19	Section 3.9, Pg. 21 – The following language was deleted: “Every PT study is open for 45 days from the day the PTs are shipped to the laboratories”.
4	11/26/19	Section 5.1, Pg. 23 – The following language was deleted: “SIM analysis of PT Samples is not required to maintain Certification. However, PT Samples analyzed using SIM, will be evaluated and graded the same as for any other single-analyte or multi-analyte group as described in Sections 5.0 and 5.2 through 5.7”.
4	11/26/19	Section 5.1, Pg. 23 – The following language was added: “SIM analysis of PT Samples is not required to maintain Certification. However, if it is the routine method of analysis for a particular analyte, then analysis of that analyte utilizing SIM shall be required. PT Samples analyzed using SIM, will be evaluated and graded the same as for any other single-analyte or multi-analyte group as described in Sections 5.0 and 5.2 through 5.7”.
4	11/26/19	Section 5.1, Pg. 23 – The following language was deleted: “If unacceptable results are obtained, remedial PT Samples must also

		be analyzed using SIM”.
4	11/26/19	Section 5.1, Pg. 23 – The following language was added: “If unacceptable results are obtained using SIM, remedial PT Samples must also be analyzed using SIM”.
4	11/26/19	Section 5.5, Pg. 26 – The following language was deleted: <ul style="list-style-type: none"> • Toxicity Characteristic Leaching Procedures (TCLP) PT Sample analysis is not required for TCLP.
4	11/26/19	Section 5.5, Pg. 27 – The language in red was added: In order to evaluate PCB PT results consistently, NC treats them as a single analyte parameter (i.e., any unacceptable result will be considered a parameter miss and require analysis of a remedial PT Sample for the entire parameter). Laboratories must report acceptable results (including “less than” values at the laboratory’s reporting limit) for all Aroclors in order for the cumulative result to be acceptable.
4	11/26/19	Attachment 2. Notice of Intent to Decertify Inorganic Method Letter, Pg. 45 – Updated
4	11/26/19	Attachment 3. Notice of Intent to Decertify Organic Method Letter, Pg. 46 – Updated
4	11/26/19	Attachment 4. Decertification Effective Date Letter, Pg. 47 – Updated
4	11/26/19	Attachment 5. Decertified Laboratory Report (For Commercial Laboratories), Pg. 49 – Updated
4	11/26/19	Attachment 11. PT Evaluation Letter – Unacceptable Results, Pg. 56 – Updated
4	11/26/19	Attachment 12. PT Evaluation Letter – Acceptable Results Complete, Pg. 58 – Updated
4	11/26/19	Attachment 13. PT Evaluation Letter – Acceptable Results Incomplete, Pg. 59 – Updated
4	11/26/19	Attachment 14. Provisional Certification Notification Letter, Pg. 60 – Updated
5	2/19/20	Section 2.49, Pg. 9 – The following language was added: “Results graded as Unacceptable by the PT Vendor for “less than” and “greater than” values may be re-evaluated as Acceptable by the NC WW/GW LC Program (See Section 5.0).”
5	2/19/20	Section 5.0, Pg. 22 – The following language was deleted: “The NC WW/GW LC Program will follow the 2009 TNI Standard for PT Sample results reporting and grading.”
5	2/19/20	Section 5.0, Pg. 22 – The following language was added: “Accredited PT Sample Providers are currently being required to follow Volume 3, Section 5.9 of the 2016 TNI Standard for PT Sample results reporting and grading. For Water Pollution (WP) studies, the Accredited PT Sample Providers use the same pooled-result grading system used formally by EPA when determining whether a result is scored “Acceptable” or “Not Acceptable”.

		<ul style="list-style-type: none"> • An “Acceptable” PT Sample result is one where the reported value falls within the acceptance limits. • A “Not Acceptable” grade is assigned when the submitted PT Sample result falls outside the acceptance limits.”
5	2/19/20	<p>Section 5.0, Pg. 22 – The following language was deleted:</p> <p>“The 2009 TNI standard evaluations of less than (<) values are listed below:</p> <ul style="list-style-type: none"> a) As “Acceptable” when the assigned value is greater than “0” and the value reported with the less than (<) sign is greater than the lower acceptance limit. b) As “Not Acceptable” when the assigned value is greater than “0” and the value reported with the less than (<) sign is less than the lower acceptance limit. c) As “Acceptable” when the assigned value is equal to < PTRL (Proficiency Testing Reporting Limit).”
5	2/19/20	<p>Section 5.0, Pg. 22 – The following language was added:</p> <p>“1) Greater-than value reporting (“>”) and scoring of all “>” results: If a laboratory reports results that are qualified with a “>” symbol, those results will be scored as “Not Acceptable” under the 2016 TNI Standard. Please note that this scoring protocol will also be applied to quantitative microbiology results and may conflict with historically acceptable and method-allowable reporting practices, particularly for most probable number (MPN) methods.</p> <p>2) Less-than value reporting (“<”): Similar to the 2003 TNI Standard, there is an emphasis on laboratories being able to quantitate and report down to the TNI Proficiency Testing Reporting Limits (PTRLs). If a laboratory uses a method that is incapable of detecting a PT analyte down to the PTRL, the laboratory risks reporting a false negative result when an analyte is spiked into the PT sample. If the analyte is spiked into a PT sample, a reported result of <PTRL, <LOQ, or a value of “0” will receive an evaluation of “Not Acceptable”.”</p>
5	2/19/20	<p>Section 5.0, Pg. 23 – The following language was deleted:</p> <p>“This means that the laboratory shall report the analytical results for PT Samples as follows:”</p>

5	2/19/20	Section 5.0, Pg. 23 – The following language was added: “NC requires laboratories to report analytical results for PT Samples as follows:”
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Attachment 1. Notice of Missed Proficiency Testing Deadline Letter

Header Subject to Change

Subject: North Carolina Wastewater/Groundwater Laboratory Certification
Proficiency Testing Results

Dear :

The North Carolina Wastewater/Groundwater Laboratory Certification (NC WW/GW LC) program did not receive proficiency testing (PT) results for the methods listed below by the September 30, deadline.

Failure to submit PT sample results to this office by the September 30, deadline constitutes a first unacceptable result for the following analyte(s) and/or parameter method technology(s):

Parameter/ Analyte	Method	Comment	Remedial PT/CAR Due Date
		Unacceptable; no value provided by deadline	12/31/

A corrective action report (CAR) detailing why the deadline was missed and how future recurrence will be prevented is required for the analyte(s) listed above.

All remedial PT results and corrective action reports must be completed and the graded result submitted by the vendor directly to this office by December 31, . You may want to consider a quick turnaround type PT sample in order to meet this deadline. Failure to submit corrective action reports and remedial PT results within this time period will result in a second unacceptable result and decertification or provisional certification may be recommended. Failure to obtain acceptable results on the remedial PT may also result in a recommendation for decertification or provisional certification.

Contact me by email or at if you have analyzed PT samples for these parameter methods this year or have any questions concerning these program requirements.

Sincerely,

, Chemist II
Division of Water Resources

cc:

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Attachment 2. Notice of Intent to Decertify Inorganic Method Letter

Header Subject to Change

Date

Subject: NC WW/GW LC Thirty-Day Parameter Method Decertification Recommendation -

Dear :

The remedial Proficiency Testing (PT) Sample result(s) for the below Parameter Method(s) reported by your laboratory for the North Carolina Wastewater/ Groundwater Laboratory Certification (NC WW/GW LC) performance evaluation was/were unacceptable and a thirty-day parameter method decertification will be recommended. The results reported and the true values as they appear in our records are as follows:

Study	Parameter Method	Units	Reported Value	True Value	Acceptance Range	¹ Performance

¹A written Corrective Action Report (CAR) for each unacceptable result will be required prior to reissuing certification.

This is to notify you that the Laboratory Certification Branch of the North Carolina Division of Water Resources, Water Sciences Section, is considering recommending a parameter method(s) decertification to the Environmental Program Supervisor. The recommendation concerns the above-mentioned violation(s). **This is not a decertification; it is a notification of our intent to consider decertification. You will be informed in a separate communication if decertification is issued.**

Contact me immediately at (919) 733-3908 if your records do not agree with ours or if you have questions.

Sincerely,

Technical Assistance & Compliance Specialist
NC WW/GW Laboratory Certification Branch

Attachment
cc:

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Attachment 3. Notice of Intent to Decertify Organic Method Letter

Header Subject to Change

Subject: NC WW/GW LC Thirty-Day Parameter Method Decertification Recommendation - [REDACTED]

Dear [REDACTED]:

The remedial Proficiency Testing (PT) result(s) for the below Parameter Method(s) reported by your laboratory for the North Carolina Wastewater/ Groundwater Laboratory Certification (NC WW/GW LC) performance evaluation was/were unacceptable and a thirty-day parameter method decertification will be recommended. The results reported and the true values as they appear in our records are as follows:

Study	Parameter Method	Reported	Performance ¹
		<80% of compounds acceptable	UNACCEPTABLE
		<80% of compounds acceptable	UNACCEPTABLE

¹A written Corrective Action Report (CAR) for each unacceptable result will be required prior to reissuing certification.

This is to notify you that the Laboratory Certification Branch of the North Carolina Division of Water Resources, Water Sciences Section, is recommending a parameter method(s) decertification to the Environmental Program Supervisor. The recommendation concerns the above-mentioned violation(s). **This is not a decertification; it is a notification of our intent to consider decertification. You will be informed in a separate communication if decertification is issued.**

Contact me immediately at (919) 733-3908 if your records do not agree with ours or if you have questions.

Sincerely,

Technical Assistance & Compliance Specialist
Division of Water Resource

Attachment
cc: [REDACTED]

Footer Subject to Change

Attachment 4. Decertification Effective Date Letter

Header Subject to Change

CERTIFIED MAIL # [REDACTED]
RETURN RECEIPT REQUESTED

SUBJECT: Parameter Method(s) Decertification – [REDACTED]

Dear [REDACTED]:

Please be advised that under provisions of Regulations 15A NCAC 02H .0807 (b) (1) and the powers duly delegated to me, a thirty-day parameter method Decertification notice is hereby issued to the laboratory for the above parameter method(s) effective [REDACTED]. No testing for the above parameter method(s) shall be performed at your laboratory for reporting to this Department for purposes of State water, wastewater, or groundwater monitoring required under Article 21 of G.S. 143. Thirty days thereafter you may again apply for parameter recertification as detailed in 15A NCAC 02H .0808 (b) of the regulations. This decertification may be appealed to the N.C. Office of Administrative Hearings in accordance with Chapter 150B of the General Statutes.

The results your laboratory reported on Proficiency Testing (PT) Samples for the above parameter method(s) are shown on our letter dated [REDACTED] (copy attached). These results lie outside the acceptable variation limit from the true value set forth by the Accredited Proficiency Testing Sample Provider and are therefore unacceptable in accordance with Laboratory Certification Regulation 15A NCAC 02H .0803 (34).

Pursuant to 15A NCAC 2H .0807 (e) (1) through (5), laboratories decertified for any parameter method(s) must comply with the following:

- (1) A decertified laboratory is not to analyze samples for the decertified Parameter Methods for programs regulated under G.S. 143-215.1, 143-215.63, et seq., or clients reporting to these programs.
- (2) A decertified commercial laboratory must supply written notification of the decertification to clients with Division of Water Resources (formerly Division of Water Quality) reporting requirements. Within 30 days, the decertified laboratory must supply the State Laboratory with a list of clients involved and copies of the notices sent to each.
- (3) A commercial laboratory that has received a parameter decertification may make arrangements to supply analysis through another certified laboratory during any decertification periods. The decertified laboratory must supply the State Laboratory, by written notice, the name of the laboratory to be used.
- (4) A commercial laboratory decertified for all parameters cannot subcontract samples for analyses to other certified laboratories during the decertification period.
- (5) A decertified municipal or industrial laboratory must have its samples analyzed by another certified laboratory during any decertification period and supply the State Laboratory, by written notice, the name of the certified laboratory to be used.

Attached is our Decertified Laboratory Report form which provides a convenient means for providing required information concerning your laboratory and/or clients for whom State required monitoring analysis are performed. All required information must be received in this office within thirty days of the decertification effective date. Failure to provide the required information within the due date may result in further enforcement actions including both civil penalties and decertification for any or all parameters for up to one year, pursuant to 15A NCAC 2H .0807 (f).

Also enclosed is a revised Certified Parameters Listing for your certificate that removes the decertified parameter method(s) from your Certification.

If you have questions or need additional information concerning this matter, please contact me at (919) 733-3908.

Footer Subject to Change

Header Subject to Change

Sincerely,

Environmental Program Supervisor
Division of Water Resources

Attachment
cc: 

Footer Subject to Change

Attachment 5. Decertified Laboratory Report (For Commercial Laboratories)

DECERTIFIED LABORATORY REPORT	
LABORATORY NAME: <input style="width: 100px;" type="text"/>	EFFECTIVE DATE: <input style="width: 100px;" type="text"/>
DECERTIFIED PARAMETER METHOD(s): <input style="width: 100px;" type="text"/>	CERT #: <input style="width: 100px;" type="text"/>
LABORATORY TYPE – Commercial	
As a result of the above Decertification, you are required to furnish information about this facility for whom State required analyses are performed.	
Please complete the following:	
Arrangements have been made to have samples for the decertified parameter method(s) analyzed by another Certified laboratory.	
() Yes () No	
If yes, enter name and NC WW/GW LC number of the laboratory to be used.	
Cert.# <input style="width: 100px;" type="text"/> Name: <input style="width: 400px;" type="text"/>	
Address: <input style="width: 400px;" type="text"/>	
<input type="checkbox"/> Certification verified (NC WW/GW LC Office use only)	
Cert.# <input style="width: 100px;" type="text"/> Name: <input style="width: 400px;" type="text"/>	
Address: <input style="width: 400px;" type="text"/>	
<input type="checkbox"/> Certification verified (NC WW/GW LC Office use only)	
If no, explain:	
<input style="width: 400px;" type="text"/>	
<input style="width: 400px;" type="text"/>	
<input style="width: 400px;" type="text"/>	
<input style="width: 400px;" type="text"/>	
If necessary, attach additional pages.	
Within thirty days of the decertification effective date, email a copy of this form to your assigned auditor, OR mail a hard copy to:	
NCDEQ/DWR NC WW/GW Laboratory Certification Branch Attn: Dana Satterwhite 1623 Mall Service Center Raleigh, North Carolina 27699-1623	
<input style="width: 400px;" type="text"/>	
Laboratory Supervisor Name (please print)	
<input style="width: 400px;" type="text"/>	<input style="width: 100px;" type="text"/>
Laboratory Supervisor Signature	Date

Attachment 6. Decertified Laboratory Report (For Municipal, Industrial and Other Laboratories)

DECERTIFIED LABORATORY REPORT	
LABORATORY NAME: <input type="text"/>	EFFECTIVE DATE: <input type="text"/>
DECERTIFIED PARAMETER METHOD(s): <input type="text"/>	CERT #: <input type="text"/>
LABORATORY TYPE – Municipal/Industrial/Other	
As a result of the above Decertification, you are required to furnish information about this facility for whom State required analyses are performed.	
Please complete the following:	
Arrangements have been made to have samples for the decertified parameter method(s) analyzed by another Certified laboratory.	
() Yes () No	
If yes, enter name and NC WW/GW LC number of the laboratory to be used.	
Cert.# <input type="text"/>	Name: <input type="text"/>
Address: <input type="text"/>	
<input type="checkbox"/> Certification verified (NC WW/GW LC Office use only)	
Cert.# <input type="text"/>	Name: <input type="text"/>
Address: <input type="text"/>	
<input type="checkbox"/> Certification verified (NC WW/GW LC Office use only)	
If no, explain:	
<input type="text"/>	
<input type="text"/>	
<input type="text"/>	
If necessary, attach additional pages.	
<u>Within thirty days</u> of the decertification effective date, Return to:	
NCDEQ/DWR NC WW/GW Laboratory Certification Branch Attn: Dana Satterwhite 1623 Mall Service Center Raleigh, North Carolina 27699-1623	
<input type="text"/>	
Laboratory Supervisor Name (please print)	
<input type="text"/>	<input type="text"/>
Laboratory Supervisor Signature	Date

Attachment 7. Decertified Laboratory Report (For Field Laboratories)

DECERTIFIED LABORATORY REPORT	
LABORATORY NAME: <input style="width: 100px;" type="text"/>	EFFECTIVE DATE: <input style="width: 100px;" type="text"/>
DECERTIFIED PARAMETER METHOD(S): <input style="width: 100px;" type="text"/>	CERT #: <input style="width: 100px;" type="text"/>
LABORATORY TYPE – Field	
<p>As a result of the above Decertification, you are required to furnish information about this facility for whom State required analyses are performed.</p> <p>During any Decertification period, the decertified laboratory is required to have samples analyzed by another Certified laboratory and supply this Program with the name(s) of the laboratory(ies) to be used.</p> <p>Please respond to the following:</p> <p>Arrangements have been made to have samples for the decertified parameter method(s) analyzed by another Certified laboratory.</p> <p>() Yes () No</p> <p>If yes, enter name and NC WW/GW LC number of the laboratory to be used.</p> <p>Cert.# _____ Name: _____</p> <p>Address: _____ <input type="checkbox"/> Certification verified (NC WW/GW LC Office use only)</p> <p>Cert.# _____ Name: _____</p> <p>Address: _____ <input type="checkbox"/> Certification verified (NC WW/GW LC Office use only)</p> <p>If no, explain:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>If necessary, attach additional pages.</p> <p><u>Within thirty days</u> of the decertification effective date, Return to:</p> <p>NCDEQ/DWR NC WW/GW Laboratory Certification Branch Attn: Dana Satterwhite 1623 Mail Service Center Raleigh, North Carolina 27699-1623</p> <p>_____ Laboratory Supervisor Name (please print)</p> <p>_____ Laboratory Supervisor Signature</p> <p>_____ Date</p>	

Attachment 8. Notice of Decertification for Failure to Submit Information by the Due Date

Header Subject to Change

CERTIFIED MAIL # [REDACTED]
RETURN RECEIPT REQUESTED

SUBJECT: Decertification for failure to submit Information by the Due Date
[REDACTED]

Dear [REDACTED]:

Please be advised that under provisions of Regulations 15A NCAC 2H .0807 (a) (13) and the powers duly delegated to me, a one-year Decertification notice is hereby issued to the laboratory for the above cited parameter(s)/method(s) effective [REDACTED]. No testing shall be performed at your laboratory for clients reporting to this Department for purposes of State water, wastewater, or groundwater monitoring required under Article 21 of G.S. 143. This Decertification may be appealed to the N.C. Office of Administrative Hearings in accordance with Chapter 150B of the General Statutes.

In addition, and in accordance with our regulation NCAC 2H .0807 (f), Civil Penalties may be assessed against a laboratory which violates or fails to act in accordance with any terms, conditions, or requirements of the Rules in this Section or of a laboratory Certification. A laboratory is subject to both civil penalties and decertification.

Optional language in red below – There is no formal letter – you may create a letter based on the situation or refer to an email and attach pdf of that.

A final notice to your laboratory requesting submittal of the Decertified Laboratory Report form was in our letter dated [REDACTED] (copy attached). This reply was to be submitted immediately upon your receipt of the letter.

Attached is another copy of the Decertified Laboratory Report form to provide the required information pursuant to 15A NCAC 2H .0807 (e) (1) through (5). All required information must be received in this office within thirty days of receipt of this letter. Failure to provide the requested information by the date due a second time may result in further enforcement actions including both civil penalties and decertification for any or all parameters for up to one year, pursuant to 15A NCAC 2H .0807 (f).

If you have questions or need additional information concerning this matter, please contact me at (919) 733-3908.

Sincerely,

Environmental Program Supervisor
Division of Water Resources

Attachment
cc: [REDACTED]

Footer Subject to Change

Attachment 9. Parameter Method Recertification Letter

Header Subject to Change

[REDACTED]

[REDACTED]

SUBJECT: Parameter Method Recertification -

Dear [REDACTED]:

Under the authority delegated to me, I hereby issue a parameter method recertification to [REDACTED], for analysis of the above mentioned parameter method(s) effective [REDACTED]. This laboratory has satisfactorily complied with the requirements for recertification found in 15 NCAC 2H .0808(b) of the Laboratory Certification Regulation; therefore, the parameter method decertification made [REDACTED], is rescinded. Enclosed is an amended Certified Parameters Listing that includes the recertified parameter method(s).

Contact me at (919) 733-3908 if you have any questions.

Sincerely,

Environmental Program Supervisor
Division of Water Resources

Attachment

cc: [REDACTED]

Footer Subject to Change



Attachment 10. EPA DMR-QA PT Study Exemption Letter



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

MAY 8 2009

4SESD-MTSB-QAS

RECEIVED

Mr. Pat Donnelly, Branch Manager
WW/GW Laboratory Certification Branch
NC DWQ Laboratory Section
1623 Mail Service Center
Raleigh, North Carolina 27699-1623

MAY 13 2009

DWQ
LABORATORY CERTIFICATION

Dear Mr. Donnelly:

Your request for exemption from U.S. Environmental Protection Agency's (EPA) National Pollution Discharge Elimination System's (NPDES) Discharge Monitoring Report – Quality Assurance (DMR-QA) program has been reviewed by EPA, Region 4. The information you provided indicates that the North Carolina Department of Environment and Natural Resources (DENR) proficiency testing (PT) program provides adequate QA to replace EPA's DMR-QA study program. The State program components cover all areas required by EPA's program. These areas are:

1. Requirements through State codes or regulations that cover all analyses for NPDES compliance at the permittee level.
2. A proficiency testing program that requires all NPDES and/or other program laboratories to successfully analyze PT samples annually for all analyses and tests by required methodology (40 CFR 136.3 Tables 1A – 1H).
3. A database that tracks all laboratories and their PT results, noting any partial responding or non-responding permittees.
4. A program with sufficient equipment for reanalysis of failed PT sample results and the ability to decertify laboratories that have not completed a successful study within the program's allotted time frame.

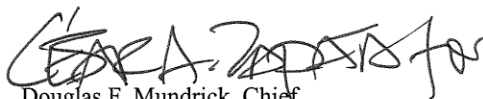
DENR's Certification Program satisfies all of the above and provides QA procedures that are as stringent as EPA's DMR-QA study program. However, proper oversight of the program will still be required for DENR to be exempt from the DMR-QA program. Annual reports (similar to a DMR-QA pass/fail report) shall be submitted to EPA Region 4, which includes the statistical information for North Carolina's WW/GW certification program with regard to DMR-QA analytes. This statistical information should include pass/fail rates for laboratories, pass/fail rates for analytes, number of laboratories in the program and number of audits conducted. Also, a review of the system after a year of operation, including an on-site assessment, will provide the information necessary to verify that the requirements of the

Region 4 DMR-QA study program have been maintained. This assessment will be performed by the Region 4 DMR-QA coordinator. After the first year, if the program adequately performs as a viable substitute for the DMR-QA program, an on-site assessment will only be made every three years, similar to the State Drinking Water Certification Program Assessments.

If these requirements are met, North Carolina's Laboratory Certification Program will continue to be a viable substitute for US EPA's DMR-QA program.

If you have any questions please contact Mr. Ray Terhune, Region 4 DMR-QA Coordinator (706) 355-8557.

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas F. Mundrick", written over a horizontal line.

Douglas F. Mundrick, Chief
Clean Water Enforcement Branch
Water Protection Division

cc: Patrick Yellin
Danny France
Marilyn Maycock
Ray Terhune
Christopher Plymale
Cesar Zapata

Attachment 11. PT Evaluation Letter – Unacceptable Results

Header Subject to Change

Date

Subject: North Carolina Wastewater/Groundwater Laboratory Certification
Proficiency Testing Results

Dear :

The North Carolina Wastewater/Groundwater Laboratory Certification (NC WW/GW LC) program has received the results from that were submitted to our office. In accordance with the provisions of the North Carolina Administrative Code, 15A NCAC 2H .0805, all certified laboratories are required to successfully analyze proficiency testing (PT) samples for each parameter method technology at least annually to maintain certification. A blind (i.e., unknown) proficiency testing sample must be analyzed for all parameters that currently appear on the laboratory's certificate attachment. Laboratories must also analyze remedial proficiency testing samples for any parameter method technology(s) graded unacceptable. Additional PT sample results, submitted voluntarily at any time during the year, will be graded similarly.

The study report(s) did not contain acceptable values for the following analyte(s) and/or parameter method technology(s):

Study	Parameter/ Analyte	Method	Comment	Remedial PT/CAR Due Date
			Unacceptable parameter; <80% of all analytes acceptable ¹	
			Unacceptable; no value provided by deadline	
			Unacceptable results	
			Unacceptable analyte; ≥80% of all analytes acceptable ²	

1 – Since < 80% of the analytes were acceptable, the entire parameter list must be reanalyzed.

2 – Since ≥ 80% of the analytes were acceptable, only the unacceptable analytes listed must be reanalyzed.

As a result of the unacceptable PT result(s) referenced above you are required to submit the following: 1) A remedial PT result (in the same matrix as the unacceptable result) and 2) a written corrective action report (CAR). All remedial PT results and CARs must be completed and the graded result submitted by the vendor directly to this office within 90 days from the date the report was issued. You may want to consider a quick turnaround type PT sample. Failure to submit CARs and remedial PT results within this time period will result in a second unacceptable result and decertification or provisional Certification may be recommended. Failure to obtain acceptable results on the remedial PT may also result in a recommendation for decertification or provisional Certification.

Contact me at [REDACTED] if you have questions concerning these program requirements.

Sincerely,

[REDACTED], Chemist I
Division of Water Resources

cc: [REDACTED]

Attachment 12. PT Evaluation Letter – Acceptable Results Complete

Header Subject to Change

Date

■

Subject: North Carolina Wastewater/Groundwater Laboratory Certification
■ Proficiency Testing Results

Dear ■:

This is to acknowledge that we have received your Proficiency Testing (PT) results from ■. Congratulations on obtaining acceptable results. **This completes all proficiency testing requirements for your North Carolina Wastewater/Groundwater Laboratory Certification for ■.**

If additional proficiency testing results are submitted voluntarily during this proficiency testing calendar year, they will be evaluated similarly and remedial PTs will be required for any results graded unacceptable.

Contact me at ■ if you have questions or if I can be of further assistance.

Sincerely,

■, Chemist I
Division of Water Resources

cc: ■

Footer Subject to Change

Attachment 13. PT Evaluation Letter – Acceptable Results Incomplete

Header Subject to Change

Date

█

Subject: North Carolina Wastewater/Groundwater Laboratory Certification
█ Proficiency Testing Results

Dear █:

This is to acknowledge that we have received your Proficiency Testing (PT) results from █. Congratulations on obtaining acceptable results.

If additional proficiency testing results are submitted voluntarily during this proficiency testing calendar year, they will be evaluated similarly and remedial PTs will be required for any results graded unacceptable.

Contact me at █ if you have questions or if I can be of further assistance.

Sincerely,

█, Chemist I
Division of Water Resources

cc: █

Footer Subject to Change

Attachment 14. Provisional Certification Notification Letter

Header Subject to Change

Date

CERTIFIED MAIL # [REDACTED]
RETURN RECEIPT REQUESTED

SUBJECT: Provisional Certification

Dear [REDACTED]:

Please be advised that under provisions of Regulations 15A NCAC 2H .0805 (a) (2) and 15A NCAC 2H .0807 and the powers duly delegated to me, a provisional certification notice is hereby issued to the laboratory for the above analyte(s)/method(s) effective [REDACTED]. Consecutive unacceptable results were reported. The results reported and the true values as they appear in our records are as follows:

Ampule/ Study	Analyte	Units	Reported	True Value	Acceptance Range	Performance
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	UNACCEPTABLE
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	UNACCEPTABLE

During this provisional certification period, the laboratory must qualify any reported results for the subject analyte(s) as "estimated" for data reported to this Department for purposes of State water, wastewater, or groundwater monitoring required under Article 21 of G.S. 143.

The laboratory must submit a written corrective action report and obtain acceptable results on two consecutive Proficiency Testing (PT) samples for the specific analyte(s) in order to rescind the provisional certification status. If the laboratory is unable to obtain acceptable results on two consecutive PT samples, decertification for the entire parameter method technology may be recommended. If acceptable results are obtained on two consecutive PT samples, the provisional certification status for those analytes will be rescinded.

The results your laboratory reported on evaluation samples for the above analyte(s) are attached. These results lie outside the acceptable variation limit from the true value set forth as acceptable in the Laboratory Certification Regulation 15A NCAC 02H .0803 (1).

Attached is our Provisional Certification Form which requests, as a result of the Proficiency Testing Evaluation(s) cited above, that certain information be reported concerning your laboratory and/or clients for whom North Carolina state required monitoring analysis are performed. The attached form must be completed and returned within thirty days of receipt. Failure to complete and return this form by the date due may result in further enforcement actions.

If you have questions or need additional information concerning this matter, please contact me at (919) 733-3908.

Sincerely,

Environmental Program Supervisor
Division of Water Resources

cc: [REDACTED]

Footer Subject to Change

Attachment 15. Provisional Certification Form - Commercial

Provisional Certification Form

Laboratory Name: _____

Effective Date: _____

Provisional Certification Analyte(s): _____

Cert #: _____

Laboratory Type - Commercial

As a result of the above provisional certification status, you are required to furnish the following information within thirty days. The laboratory may either 1) make arrangements to supply analysis for the subject analyte through another certified laboratory or 2) report the subject analyte with qualification during the provisional certification period.

Please complete the following (as it applies):

1. Client data for the analyte(s) listed above will be furnished by subcontracting to another certified laboratory. () Yes () No

If yes, enter name and certificate number of the laboratory to be used. Please note: The designated laboratory must be certified with North Carolina Wastewater/Groundwater Laboratory Certification for the subcontracted parameter.

Cert.# _____ Name: _____

Address: _____

☐ Certification verified (NC WW/GW LC Office use only)

2. Data reports will be qualified for the affected analyte(s). (✓) Yes () No
Record the qualification to be used below.

The clients involved are listed below:

<u>Client Name</u>	<u>Address</u>

If necessary, attach additional pages.

Within thirty days of the decertification effective date,

Return to:

NCDEQ/DWR

NC WW/GW Laboratory Certification Branch

Attn: Dana Satterwhite

1623 Mail Service Center

Raleigh, North Carolina 27699-1623

Laboratory Supervisor Name (please print)

Laboratory Supervisor Signature

Date

Attachment 16. Provisional Certification Form – Municipal/Industrial/Other

Provisional Certification Form

Laboratory Name: _____

Effective Date: _____

Provisional Certification Analyte(s): _____

Cert #: _____

Laboratory Type – Municipal/Industrial

As a result of the above provisional certification status, you are required to furnish the following information within thirty days. The laboratory may either 1) make arrangements to supply analysis for the subject analyte through another certified laboratory or 2) report the subject analyte with qualification during the provisional certification period.

Please complete the following (as it applies):

1. Data for the analyte(s) listed above will be furnished by contracting to another certified laboratory.
() Yes () No

If yes, enter name and certificate number of the laboratory to be used. Please note: The designated laboratory must be certified with North Carolina Wastewater/Groundwater Laboratory Certification for the contracted parameter.

Cert.# _____ Name: _____

Address: _____

☐ Certification verified (NC WW/GW LC Office use only)

2. Data reports will be qualified for the affected analyte(s). () Yes () No
Record the qualification to be used below.

The permits involved are listed below:

<u>Facility/Location</u>	<u>Permit #</u>

If necessary, attach additional pages.

Within thirty days of the decertification effective date, Return to:

NCDEQ/DWR
NC WW/GW Laboratory Certification Branch
Attn: Dana Satterwhite
1623 Mail Service Center
Raleigh, North Carolina 27699-1623

Laboratory Supervisor Name (please print)

Laboratory Supervisor Signature

Date

Attachment 17. Provisional Certification Rescission Letter

Header Subject to Change

SUBJECT: Provisional Certification Rescinded -

Dear :

This is to acknowledge that we have received your Proficiency Testing (PT) results from . Congratulations on obtaining acceptable results. This laboratory has satisfactorily analyzed the required remedial PTs; therefore, the provisional certification status made effective , is rescinded. You may report the subject analyte(s) without qualification beginning immediately.

Contact me at (919) 733-3908 if you have any questions.

Sincerely,

Environmental Program Supervisor
Division of Water Resources

cc:

Footer Subject to Change

Attachment 18. Example Root Cause Analysis

Root Cause Analysis (RCA) is a technique used in problem solving to identify the underlying reason why something has gone wrong or why a difficulty has occurred. It is a step-by-step method that leads to the discovery of a fault's first or core cause. In compliance testing, the root cause analysis often takes the investigator back to the laboratory's quality system protocols.

Root cause analysis may include the following actions and checks: Raw data and calculations, laboratory reagent water criteria, the suitability of chemical reagents used in the test, the expiration dates of calibration and check standards, instrument calibration, responses and maintenance, sample conditions upon delivery to the laboratory and storage conditions or preservation if applicable, workplace cleanliness, staff training and competency, standard operating procedures, data entry and review processes, undue job pressures, etc. There are a variety of problem-solving tools that may be employed to diagnose the problem including flowcharts, cause and effect diagrams (also referred to as fishbone diagrams) or any combination used to drill down to cause of the problem. A simplified iterative process often used in root cause analysis is the *Five Whys* method. An investigator would continue asking "Why did this happen?" until they arrive at the root cause. Refer to the following example:

The laboratory obtains unacceptable results on a semivolatile organic proficiency testing (PT) sample and asks the following:

Why did this happen? A review of the raw data package reveals that the software improperly integrated a peak.

Why? The result was reported from this integration because the analyst was not aware that when this occurs, manual integration must be performed.

Why? Manual integration is not addressed in the standard operating procedure or in a stand-alone procedure and training in manual integration using the software has not been provided.

Why? The new organic unit supervisor has also not been trained in the software with respect to the ability to manually integrate peaks when necessary.

Why? A documented system for training in all aspects of calibration and quantitation of semivolatile organic target analytes has not been implemented in the laboratory's quality system.

The corrective action plan would then include steps to eliminate failure at each of these points in the process, beginning with the root cause. The ultimate goal of Root Cause Analysis (RCA) is to eliminate the core cause of the problem. If a corrective action, or a series of actions, is implemented and only corrects the symptoms and does not eliminate the cause – the process leaves the possibility of recurrence.

Corrective Action Report (CAR)

A Corrective Action Report is a report detailing the measures taken to eliminate or prevent the recurrence of the causes of an existing out-of-control event, nonconformity or undesirable condition. It is a retrievable documentation of those actions and follow-up monitoring to ensure resolution. A good Corrective Action Report addresses and documents the following:

- the existing problem – describe the problem referencing specific data and dates,
- the root cause of the problem,
- corrective actions taken to correct the problem and actions taken to prevent recurrence,
- future monitoring to check resolution – describe quality of data after corrective action
- implementation referencing specific data and dates – is further corrective action needed, and
- data that required qualification or rejection as a result of this problem.

The format of this report is up to the individual laboratory. It may be written in a narrative format, entered into a table or documented on a template form. An example CAR form is given below.

Example Corrective Action Report Form

Lab Name	Corrective Action Report (CAR)
	Document Control #:
	Effective Date:
Non-conformance type:	<input type="checkbox"/> Sampling <input type="checkbox"/> Sample Receiving <input type="checkbox"/> Proficiency Testing <input type="checkbox"/> Calibration <input type="checkbox"/> Analysis <input type="checkbox"/> QC <input type="checkbox"/> External Audit <input type="checkbox"/> Other:
CAR Initiated by:	Date Initiated:
Description of Non-conformance:	
Description of Root Cause Analysis:	
Corrective Actions Taken to Prevent Recurrence:	
Sample Data Requiring Qualification/Rejection:	
Follow-up Investigation/Continuous Monitoring:	
Corrective Action Successful: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Supporting Documents Attached: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Date CAR Closed:	

Have PT results been submitted for all parameters on the certificate attachment for the current or previous (circle one) PT Calendar Year?

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
--------------------------	-----	--------------------------	----

Are/were PT results submitted to this office by September 30?

☐ Yes ☐ No

Does the laboratory use an approved PT provider accredited by: A2LA or ACLASS (circle one)? List the PT provider here:

☐ Yes ☐ No

Are known PTs analyzed with initial blind PTs? [NOTE: Known PTs are acceptable for troubleshooting purposes with remedial PTs but should not be analyzed with the maintenance PTs if this is not routine for environmental samples.]

☐ Yes ☐ No

Are PT results reported to NC WW/GW LC directly from the PT provider?

☐ Yes ☐ No

Are remedial PTs analyzed within 90 days of the initial failed PT report issue date?

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
--------------------------	-----	--------------------------	----

Does the lab have an EPA Lab Code? Note the EPA Lab Code here:

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
--------------------------	-----	--------------------------	----

Is the EPA Lab Code reported with PT results?

☐ Yes ☐ No

Is PT sample preparation documented?

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
--------------------------	-----	--------------------------	----

Are PT sample analyses documented in the same manner as routine environmental samples?

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
--------------------------	-----	--------------------------	----

Are PT samples analyzed in the same manner as routine environmental samples (e.g., without additional QC, single analysis, TRC analyzed on same spectrophotometer program, etc.)?

☐ Yes ☐ No

Are PT samples equally distributed among qualified personnel from year to year?

☐ Yes ☐ No

Comments:

Are PT sample results reported with the correct method codes?

☐ Yes ☐ No

Are PT sample results reported to the routine PQLs?

	Yes	No
--	-----	----

If PT results are submitted to the vendor electronically, is a hard copy of the data entry retained?

☐ Yes ☐ No

Are PT records retained for five years?

☐ Yes ☐ No

Did the lab receive the annual PT letter?

☐ Yes ☐ No

Have lab personnel reviewed or have access to the PT Guidance Doc.? Revision #:

	Yes	No
--	-----	----

Additional Comments: